

FIG. 1

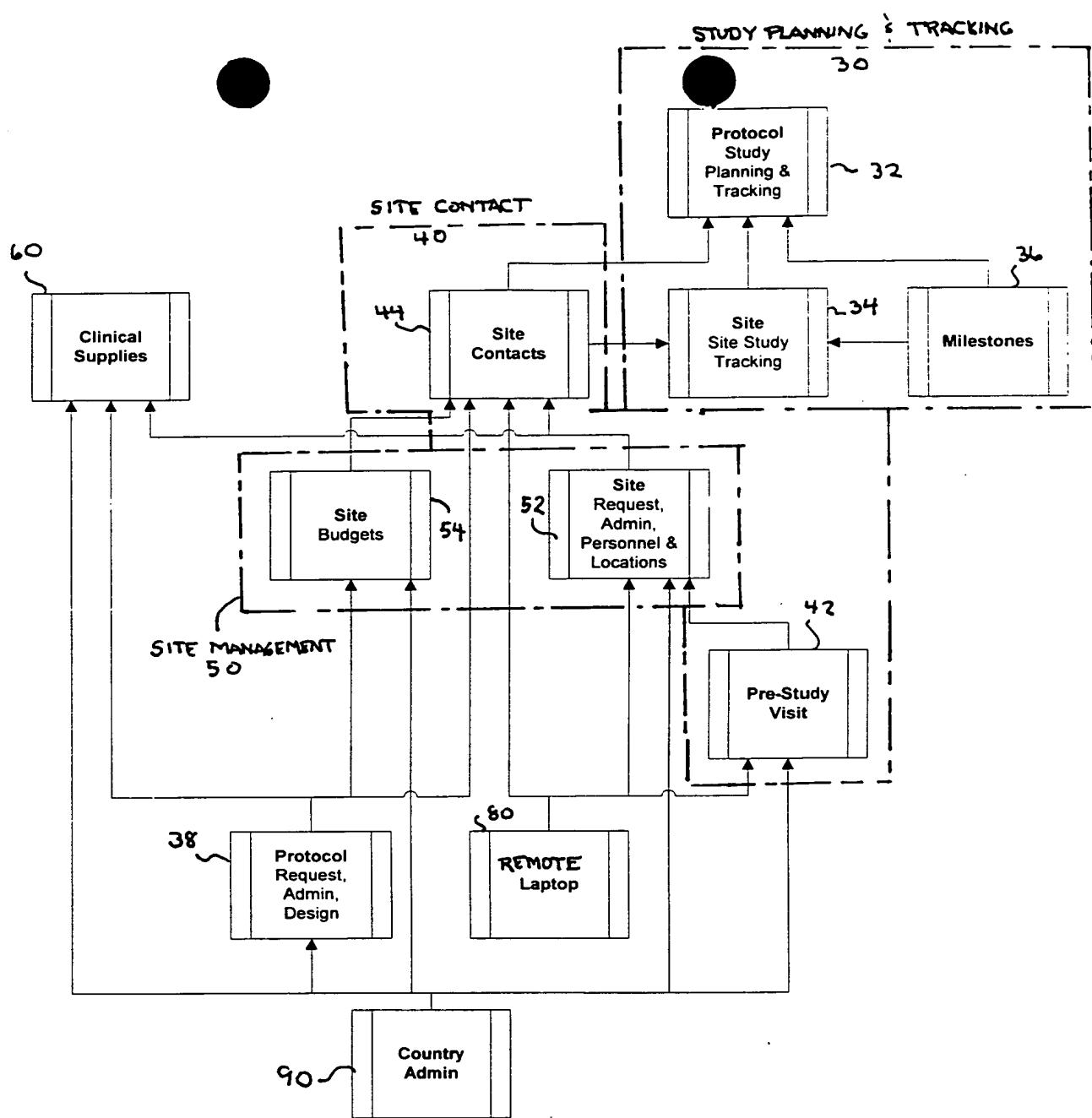
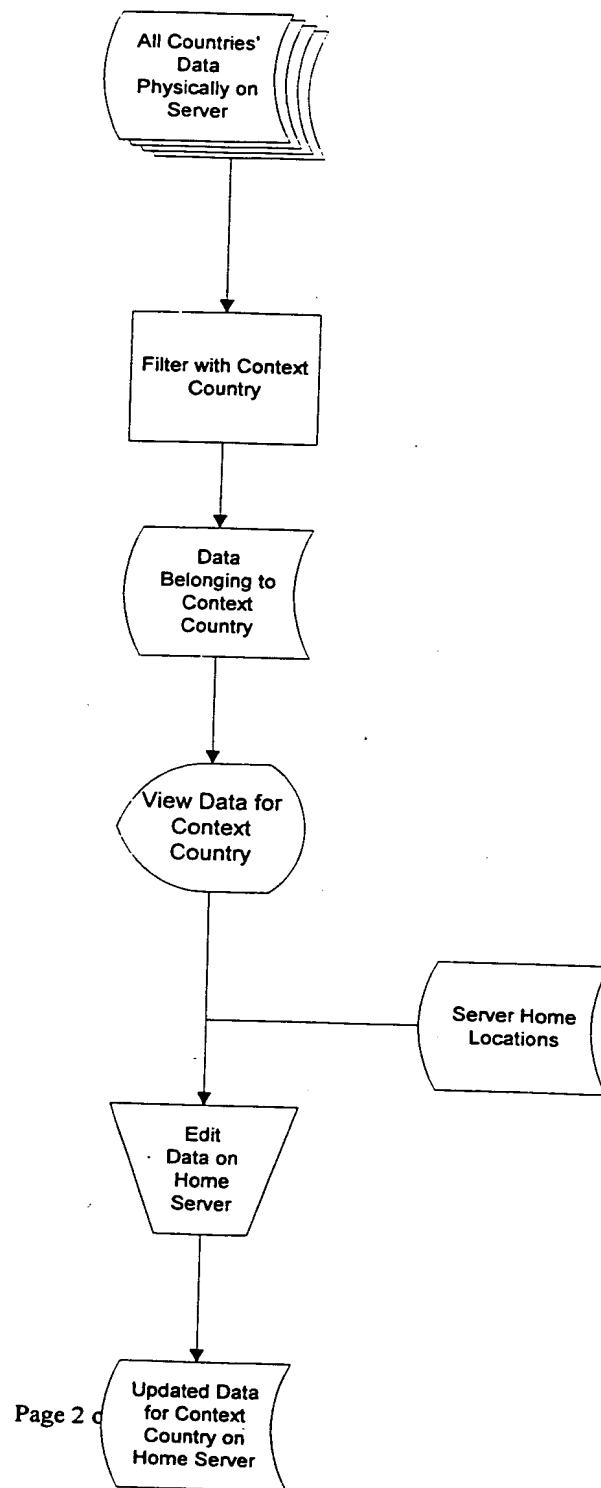


FIG. 2

Data Flow Diagram
Module: **Architecture**
Section: **Multi-Country**

Fig. 3



THE PROTOCOL NUMBER REQUEST SCREEN

PROSIT - Never Never Land

Protocol Number Request

File Edit View Actions Modules Window Help

Protocol Site County Administration Pre-Study Visit Site Contact Milestones Clinical Supplies Reports Study Planning

Protocol ID	Status	Date	Site	Requester	Reviewer	Protocol Number	Protocol Title	
RQ - 0000001	Open	01-MAR-19	Laptop	Pan, Peter J.	Darling, Wendy	** - 000012	Mometasone vs. Budesonide in Asthma	
RQ - 0000002	Open	26-MAR-19	Milestones	Pan, Peter J.	Darling, Wendy	** - 000065	Mometasone vs. Budesonide in Asthma	
RQ - 0000003	Open	26-MAR-19	Clinical Supplies	Pan, Peter J.	Darling, Wendy		Comparative Study of Topical Corticosteroids	
RQ - 0000004	Open	26-MAR-19	Reports	Pan, Peter J.	Darling, Wendy		Effects of rHuL-10 on Cytochrome P450 3A4	
RQ - 0000005	Open	26-MAR-1998	SUBMITTED	Never Never Land	Pan, Peter J.	Medicine, Chief	Absorption, Metabolism and Excretion	
RQ - 0000006	Open	26-MAR-1998	SUBMITTED	Never Never Land	Pan, Peter J.	Darling, Wendy	Endometrial Histologic Effects of Oral Contraceptives	
RQ - 0000007	Open	26-MAR-1998	RETURNED	Never Never Land	Pan, Peter J.	Medicine, Chief	Comparison of Mometasone Furoate and Beclomethasone Dipropionate	
RQ - 0000010	Open	31-MAR-1998	ASSIGNED	Never Never Land	Pan, Peter J.	Medicine, Chief	** - 000112	Comparison of Mometasone Furoate and Beclomethasone Dipropionate
RQ - 0000079	Open	03-APR-1998	SUBMITTED	Never Never Land	Pan, Peter J.	Darling, Wendy		Mometasone
RQ - 0000080	Open	08-APR-1998	ASSIGNED	Never Never Land	Pan, Peter J.	Darling, Wendy	** - P00008	Mometasone vs Budesonide in Asthma
RQ - 0000103	Open	07-MAY-1998	SUBMITTED	Never Never Land	Pan, Peter J.	Darling, Wendy		Mometasone vs Budesonide in Asthma

5/8/98 9:20:23

Fig. 4

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PROSIT - UNITED STATES

File Edit Actions Modules Window Help

Protocol Number Request Details [New]

Request No:	Submit Date:	Status: NEW
Schering No:	Schering Name:	<input type="button" value="Print"/>
Requester:	Rispoli, Marc C	<input type="checkbox"/> SPRI US IND: <input checked="" type="checkbox"/>
Project Physician:		<input type="checkbox"/> International: <input checked="" type="checkbox"/>
Program:		
Mktd. Dose Form:		
Project Accounting Code:		
Monitoring Area:		
Expense Center:	1477 - RESEARCH SYS	
Phase:		
Protocol Type:		
Working Title:		

K/S 5

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Protocol Administration: I - P00324

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Working Title: testing the new Prosit build version 1.04

Administration | Personnel | External Organizations

Protocol Status

Protocol Status: Amendment In Progress Study Status: PLANNED Active:

Finalize Date: 04-NOV-1998 Notification: Notif. Date:

Notif. Reason:

Administration/Accounting

Therapeutic Team: Expense Center: 1477 - RESEARCH SYS

Program: INTERNATIONAL ALLERGY Mod. Dose Form: ALKM SPINJ

Project Acc. Code: FD1 - 000049 - 303E Originating Sub: UNITED STATES

Monitoring Area: MEDICAL AND SCIENTIFIC AFFAIRS Amend. Version: 1 Event Manager:

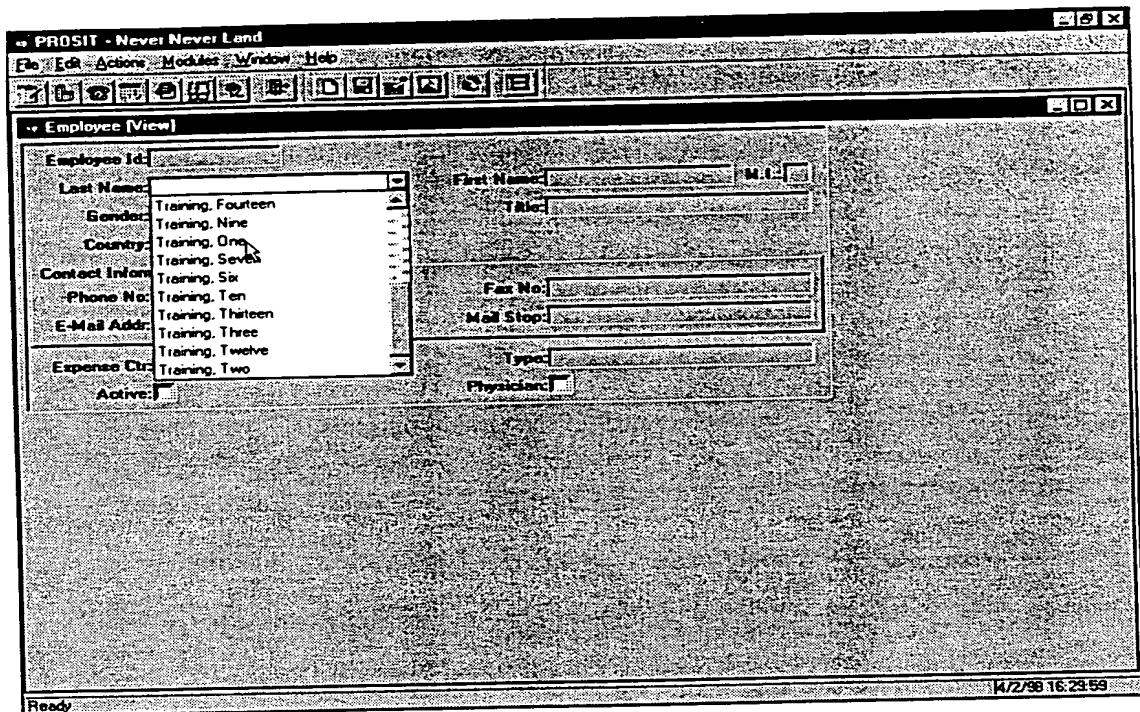
Protocol Type: I - MEDICAL RESEARCH INTERNATIO Final Amend. Date:

The name of an outside organization or company that is working with SP on some aspect of the study 05-Jan-1999

Fig. 6

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EMPLOYEE ROSTER SCREEN



09655667 096500

PROTOCOL DESIGN

...PROSIT NEVER NEVER LAND...

File Edit View Actions Modules Window Help

Protocol Design: 000UD5

Protocol: 000065 Schering No: 1032098 Schering Name: MOMETASONE

Working Title: Mometasone vs. Budesonide in Asthma

Design: Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Working Title: Mometasone vs. Budesonide in Asthma

Protocol Title: Efficacy and safety of mometasone furoate dry powder and budesonide powder (pulmicort turbhaler) in the treatment of asthma

Primary indication: 493 ASTHMA

IND/HA Ref No: Phase: PHASE III

Study Population: ADULTS

Data Collection Tool: CRF

Synopsis:
Salbutamol MDI acceptable for reversibility

THE MEDICATION TAB

PROSIT - NEVER NEVER LAND

File Edit View Actions Module Window Help

Protocol Design: 000065 Schering No: 032068 Schering Name: MDOMETASONE

Working Title: Homotetacne VEL BUSENOYL Acetate

Design Medication Visit Map Procedures Optional Fields Subject Entry Study Objectives

Test Drug Number Test Drug Name Role Amendment ID

032068 MDOMETASONE PRIMARY

Text drug number can not be modified once saved, to change a test drug number delete it and re-add it.

Strength	Regimen	Dose Form	Route	Amendment ID
100 mcg	2x daily	INHAL PWD	INTRANASAL	
200 mcg	2 on 4x daily	INHAL PWD	INTRANASAL	
4				

4/3/98 13:30:32

Ready

F. S. 9

VISIT MAP

PROSIT - NEVER NEVER LAND

File Edit View Actions Modules Window Help

Protocol: 000065 Schering No: 022089 Schering Name: MOMETASONE

Working Title: Montelukast vs. Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Visit	Visit Label	Study Phase	Prev Visit ID	Date Since Prior Visit	Enrollment Min	Enrollment Max	Assessment ID
1	Test Recruitment	SCREENING		0	0	0	
2	Baseline	TREATMENT	1	7	14		
3	1st Evaluation	TREATMENT	2	5	5		
4	2nd Evaluation	TREATMENT	3	5	5		
5	Final Evaluation	FOLLOW-UP	4	25	31		
6	1st Evaluation Short	TREATMENT	2	7	14		
7	Final Evaluation Short	FOLLOW-UP	6	25	31		
8			7				

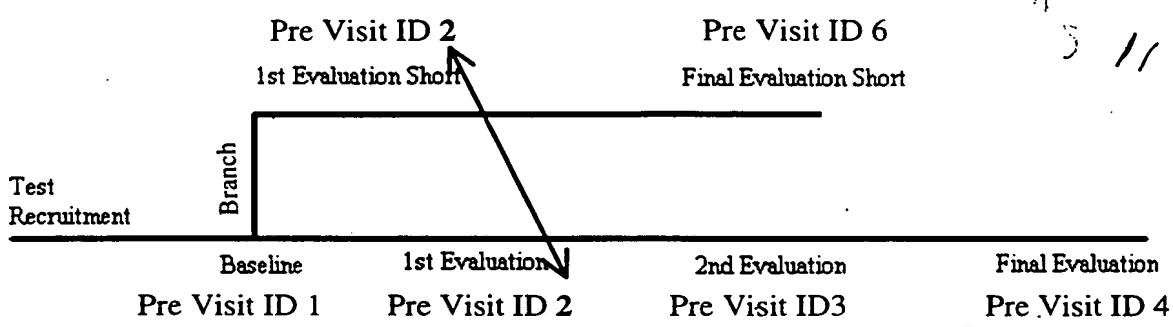
This is a descriptive label for the visit.

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DIFFERENT TREATMENT SCHEDULES CONT.



00000000000000000000000000000000

PROCEDURES TAB

PROSIT - Never Never Land

File Edit View Actions Modules Window Help

Protocol: 000065 Schering No: 032080 Schering Name: MOMETASONE

Working Title: Mometasone vs. Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Treatment Schedule: Treatment Schedule 1

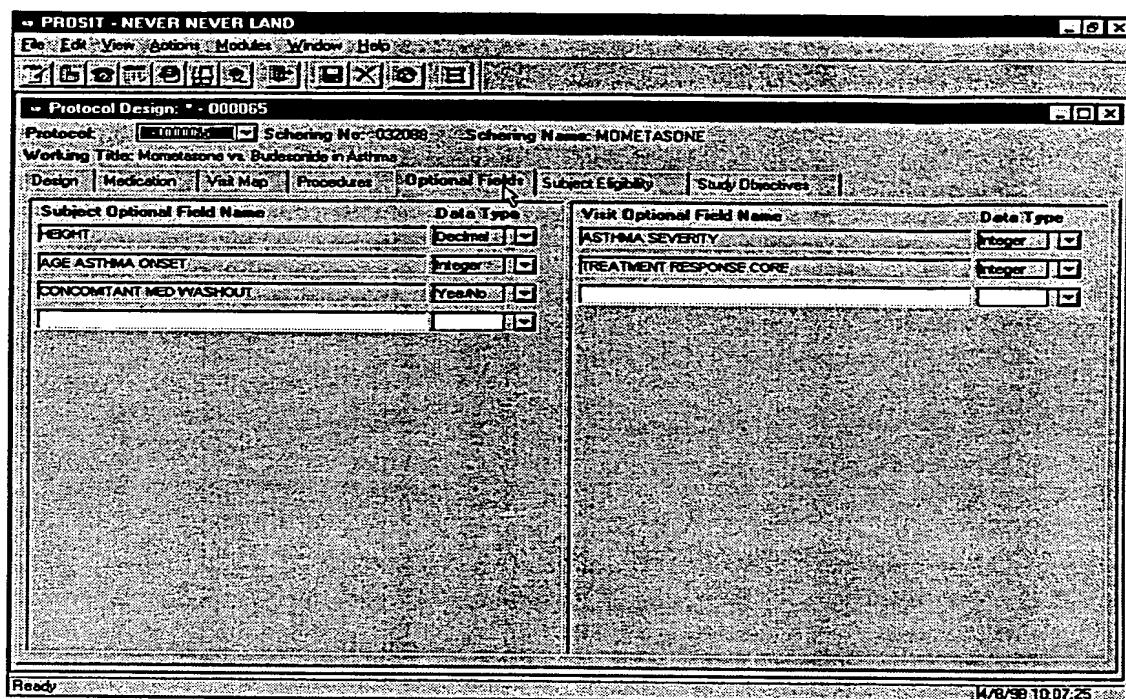
Procedure Name	Visit 0	1	2	3	4	5
LABORATORY EVALUATION	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MEDICAL HISTORY	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
VITAL SIGNS	<input checked="" type="checkbox"/>					
PHYSICAL EXAMINATION	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
ECG	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

This is the label for identifying the study treatment

4/3/98 16:04:40

A. S. 12

OPTIONAL FIELDS



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SUBJECT ELIGIBILITY

PROSIT - Never Never Land

File Edit View Actions Modules Window Help

Protocol: P00008 Screening No: 032098 Screening Name: MOMETASONE

Working Title: Mometasone vs Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Reason for Ineligibility

EXCLUDED CONCOMITANT MEDICATION
DO NOT MEET ENTRANCE CRITERIA
SUBJECT DOES NOT WISH TO PARTICIPATE
EXCLUDED CONCOMITANT ILLNESS

Reason for Discontinuation

1.5.14

DID NOT MEET ENTRANCE CRITERIA NC
DISEASE IS NOT SEVERE ENOUGH DN
DISEASE IS TOO SEVERE DS
EXCLUDED CONCOMITANT ILLNESS EI
EXCLUDED CONCOMITANT MEDICATION EM
HISTORY IS NOT APPROPRIATE FOR ENTRY HN
RECENT EXCLUDED HOSPITALIZATION OR PROCEDURE EH
SUBJECT AGE IS NOT APPROPRIATE SA
SUBJECT DID NOT RETURN FOR SCREENING SS
SUBJECT DIED PRIOR TO SCREENING SD

This is the reason why the subject would be considered ineligible

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REASONS FOR DISCONTINUATION CONT.

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1.5.13

.. PROSIT - Never Never Land

File Edit View Options Modules Window Help

Protocol: P00008 Screening No: 102008 Screening Name: MOMETASONE

Working Title: Mometasone vs Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Reason for Ineligibility

EXCLUDED CONCOMITANT MEDICATION
PREGNANCY
DISEASE IS TOO SEVERE

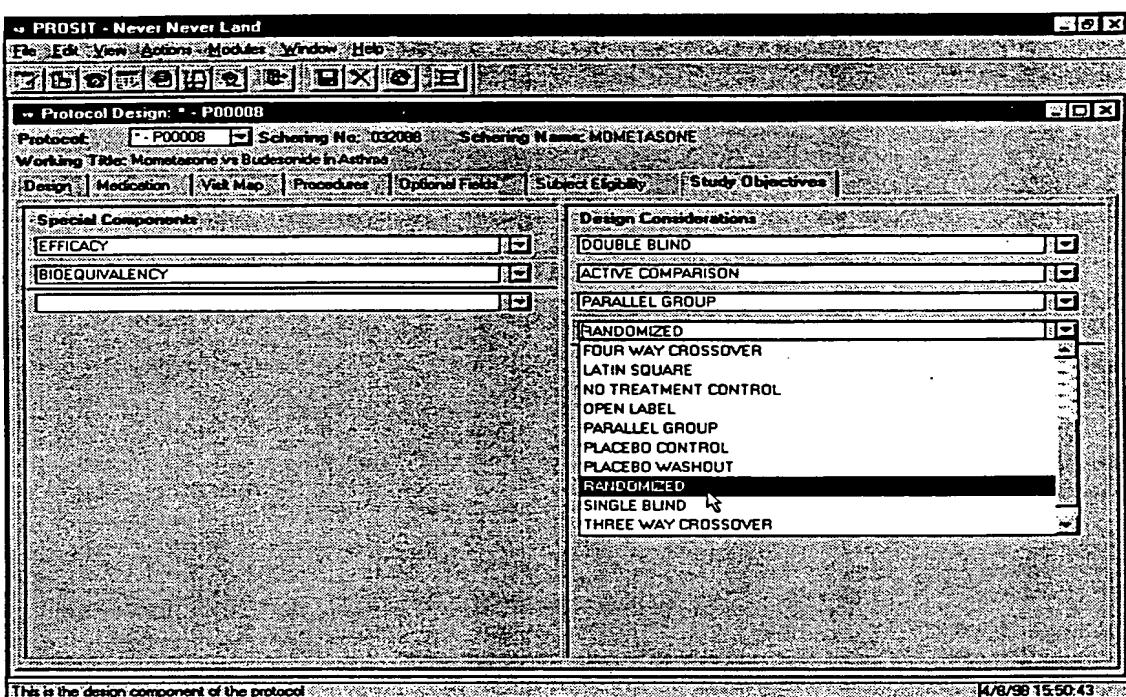
Reason for Discontinuation

ADVERSE EVENT
PRE-ATRO
TREATMENT FAILURE, OVERALL DX STATUS MOD/SEVERE
LOST TO FOLLOWUP
INVESTIGATOR DEEMS IT IS NOT IN SUBJECTS BEST INTERES
NON-COMPLIANCE
DID NOT MEET PROTOCOL ELIGIBILITY

ADMINISTRATIVE	70
ADVERSE EVENT	10
CLEARED	80
COMPLETE	00
DEATH	99
DID NOT ENTER NEXT PHASE	51
DID NOT MEET CROSSOVER REQUIREMENTS	64
DID NOT MEET PROTOCOL ELIGIBILITY	60
DID NOT MEET PROTOCOL REQUIREMENTS	63
DID NOT MEET RANDOMIZATION CRITERIA	65

This is the reasons why a subject would be discontinued 4/6/98 15:48:13

DESIGN CONSIDERATIONS



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CREATING AN AMENDMENT

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Protocol: 2008 Schering Name: MOMETASONE

Working Title: Amendment

Protocol: 2008 Schering Name: MOMETASONE

Working Title: Amendment

Protocol Status: Finalized Study Status: ENROLLMENT ONGOING Active:

Finalize Date: 12-MAR-1998 Notifications: Notiz. Date:

Notiz. Reason:

Administration/Accounting Therapeutic Team: ALLERGY/ASTHMA (ALLERGY II) Expense Center: 5834 - MGT DEVEL & PLANNING

Progress: LINE EXTENSION ALLERGY NIM. Dose Form: ORAL POWD-GMP

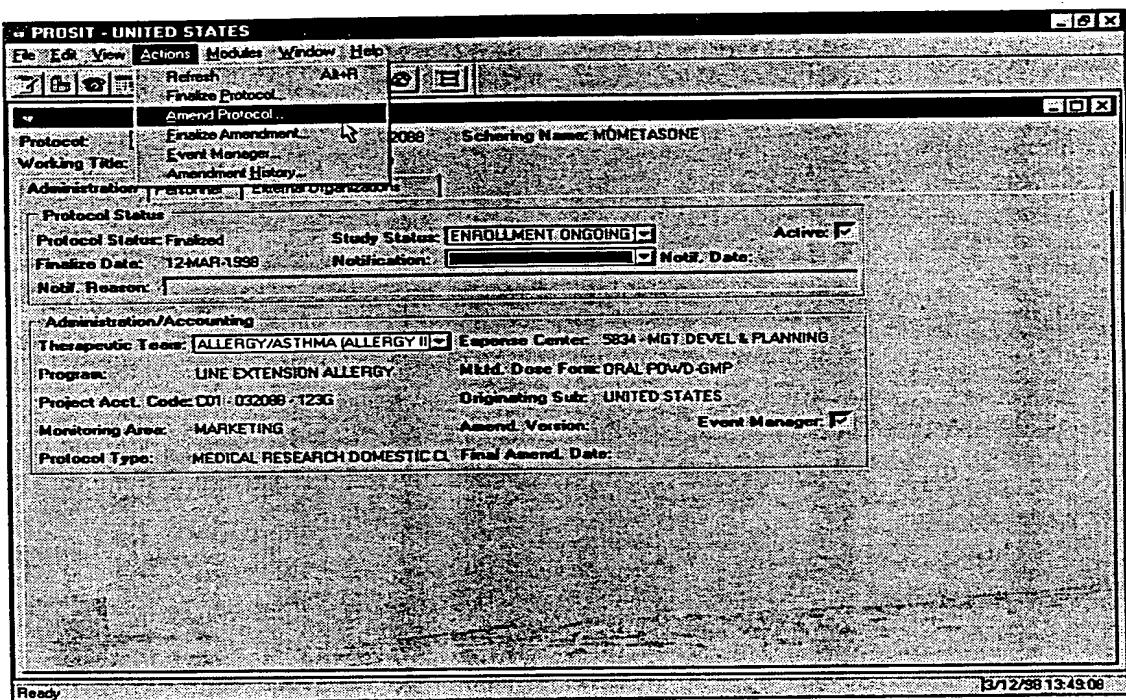
Project Act. Code: 001-032088-123G Originating Sub: UNITED STATES

Monitoring Area: MARKETING Amend. Version: Event Manager:

Protocol Type: MEDICAL RESEARCH DOMESTIC CL Final Amend. Date:

Ready 13/12/98 13:49:00

H/S. 17



T-S. 18

Seq	Task Name	Task Type	Task ID	Milestone Indicator			
1	Completion of Clinical protocol	SIMPLE	50	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Investigator Agreement Sent to HQ	SIMPLE	23	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Curriculum Vitae of Principal Investigator(s)	SIMPLE	39	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	CV of Laboratory Director(s) Received in S	SIMPLE	43	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Informed Consent Task(Trans)	SIMPLE	26	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Gov. Regulatory App. (w/trans.) Received in S	SIMPLE	30	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	CV of Laboratory Director(s) Received in Sub.	SIMPLE	34	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	this is a new master task that was created by mark fung-a	SIMPLE	130	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	this is another very long task name that was created on the s	SIMPLE	141	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Site Administration	SIMPLE	447	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	Site Administration -Location\Personnel	SIMPLE	448	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	Site Administration -Personnel and location	SIMPLE	457	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	mark	SIMPLE	2480	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	Site Administration	SIMPLE	499	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	First Data Discrepancy Report Available	SIMPLE	520	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	Master Task Comm	SIMPLE	559	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17	First Subject/First Visit (Protocol)	SIMPLE	570	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18	Root	SIMPLE	270	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19	Design Start	SIMPLE	48	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	Primary Stat Analysis Results Released	SIMPLE	15	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Rollup Task Name	Type	System ID

Ready

05-Jan-1999

F-9 19

PROSIT - UNITED STATES

File Edit View Modules Window Help

Core Task List

Core Task List Core Site Instructions

Seq	Name	Task Type	Milestone Indicator
1.	Protocol Number Assigned	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
2.	Final Protocol Date	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
3.	Final CRF/RDE Screens Available	SIMPLE	<input checked="" type="checkbox"/>
4.	First Site Initiated	SUMMARY	<input checked="" type="checkbox"/>
5.	First Subject Enrolled(Protocol)	SUMMARY	<input checked="" type="checkbox"/>
6.	First Subject First Visit	SUMMARY	<input checked="" type="checkbox"/>
7.	Enrollment Cutoff (Protocol)	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
8.	Last Subject / Last Visit (Protocol)	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
9.	Last CIVE/Data Discrepancy In-House	SIMPLE	<input checked="" type="checkbox"/>
10.	Data Cleanup Complete (Protocol)	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
11.	Database Locked	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
12.	Primary Stat Analysis Results Released	SIMPLE	<input checked="" type="checkbox"/>
13.	Final Statistical Results Released	SIMPLE	<input checked="" type="checkbox"/>
14.	Final Data Listings Released	SIMPLE	<input checked="" type="checkbox"/>
15.	Final PCS Date	SIMPLE	<input checked="" type="checkbox"/>
16.	Last Data In-house/SPRI HQ(Protocol)	EVENT-MANAGER SIMPLE	<input checked="" type="checkbox"/>
17.	Last Site Initiated (to Date)	SUMMARY	<input checked="" type="checkbox"/>
18.	(New)		

A description of a task that will be mandatory for inclusion in every site plan in this country.

INCA-01-1990

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PROSIT - UNITED STATES

File Edit View Modules Window Help

Core Task List Core Site Instructions

Seq	Task Name	Task Type Parent Name	Milestone Indicator	TA Indicator
24	Prestudy Visit Form(s) Received in Subsidiy	SIMPLE	✓	✓
25	Prestudy Visit Form(s) Sent to HQ.	SIMPLE	✓	✓
26	Protocol Signed by Investigator Rec. in Sub.	SIMPLE	✓	✓
27	First Subject Enrolled (Site)	AUTOMATIC ROLL-UP	✓	✓
28	Protocol Signed by Investigator Sent to HQ.	SIMPLE	✓	✓
29	Site Initiated	AUTOMATIC ROLL-UP	✓	✓
30	First Subject Screened	AUTOMATIC ROLL-UP	✓	✓
31	All Data In-house (Site)	MANUAL ROLL-UP	✓	✓
32	Written Ethics Committee App. (w/trans) Sent	SIMPLE	✓	✓
33	Written Ethics Committee App. (w/trans) Rec.	SIMPLE	✓	✓
34	Data Clean-up Complete (Site)	MANUAL ROLL-UP	✓	✓
35	Enrollment Complete (Site)	MANUAL ROLL-UP	✓	✓
36	this is a new master task that was created by mark tun	SIMPLE	✓	✓
37	new requirement	SIMPLE	✓	✓
38	Site Administration -Personnel and location	SIMPLE	✓	✓
39	Site Administration	SIMPLE	✓	✓
40	Site Administration	SIMPLE	✓	✓
41	this is another very long task name that was created on	SIMPLE	✓	✓
42	Milestone task added to check the duration	SIMPLE	✓	✓
43	A master task with the milestone indc	SIMPLE	✓	✓
44	(New)			

A description of a task that will be mandatory for inclusion in every site plan in this country.

05-Jan-1999

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TS. 21

PROSIT - UNITED STATES

File Edit Actions Modules Window Help

Template Tab Folder

Template: 1352 Changed: 12/10/98 Country: UNITED STATES

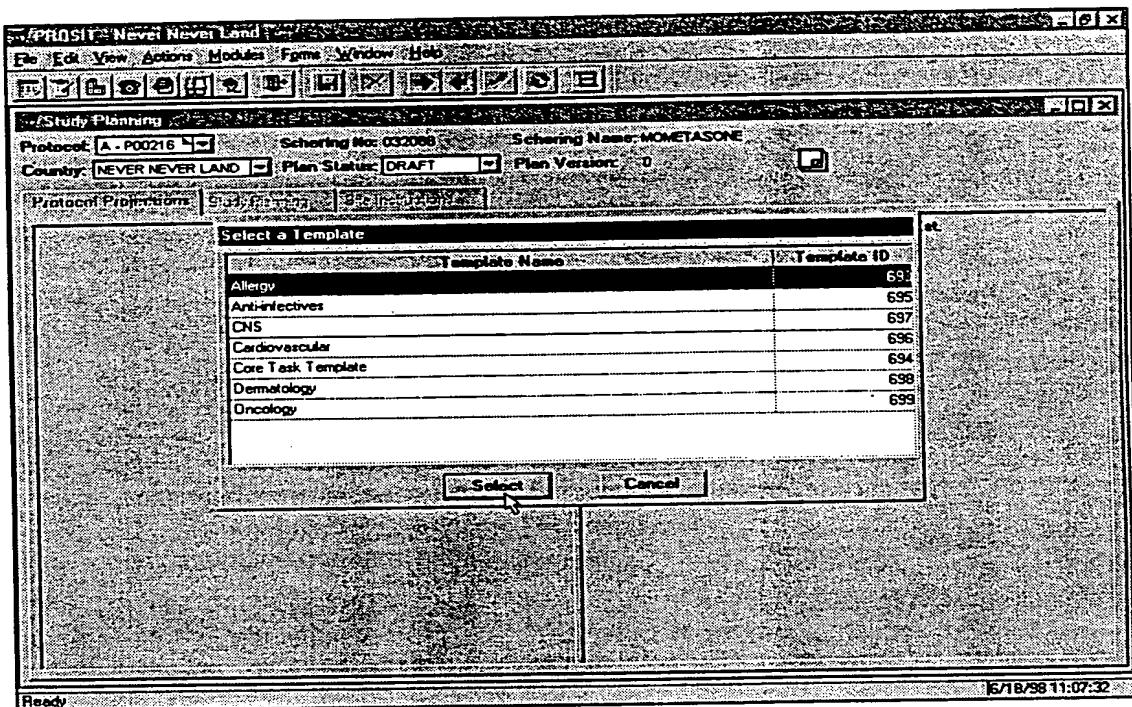
Template to test the milestone indc change

Seq.	Task Name	Days	Task Type	Milestone Indicator
1	USA-Template to test the milestone indc change	0	USER DEFINED	
2	Protocol Number Assigned	1	EVENT MANAGER SP	
3	Final Protocol Date	0	SIMPLE	
4	Final CRF/RDE Screen Date	0	SIMPLE	
5	First Site Initiated	0	SUMMARY	
6	First Subject/First Visit (Protocol)	0	SIMPLE	
7	Enrollment Complete (Protocol)	0	EVENT MANAGER SP	
8	Last Subject/ Last Visit (Protocol)	0	EVENT MANAGER SP	
9	Data Cleanup Complete (Protocol)	0	EVENT MANAGER SP	
10	Last Data Discrepancy Resolved	0	SIMPLE	
11	Database Locked	0	EVENT MANAGER SP	
12	Primary Stat Analysis Results Released	0	SIMPLE	
13	Final Statistical Results Released	0	SIMPLE	
14	Final Data Listings Released	1	SIMPLE	
15	Final PCS Date	0	SIMPLE	
16	First Subject Enrolled	0	SUMMARY	
17	First Subject First Visit	0	SUMMARY	
18	Budget Info.Sheet (signed&dated by Inv.) Rec.	0	SIMPLE	

A unique number assigned by the system to identify the template

05-Jan-1999

SELECTING A TEMPLATE



PROTOCOL PROJECTION TAB

PROSIT - Never Never Land

File Edit View Actions Modules Forms Window Help

Study Planning

Protocol: A - P00216 | Document ID: 0000003 | Scheduling Name: HOMETASONE

Country: NEVER NEVER LAND | Plan Status: DRAFT | Plan Version: 1.0

Protocol Projections | Study Planning | Site Instructions

	Planned	Latest Est.
Evaluable Subjects	40	
Subjects to Enroll	50	
Sites NEVER NEVER LAND	2	
Sites International	0	
Sites Per Monitor	2	
Sites Per HQ CRA	0	
Monitoring Interval w/o	6	
Min No Subjects Per Site	25	
Average Subjects Per Site	0	

	Planned	Latest Est.
Monitoring Countries	NEVER NEVER LAND	0
Total	0	0

Ready 6/18/98 11:09:21

1/5 2/5

STUDY PLAN

PROSIT - Never Never Land

File Edit View Actions Modules Forms Window Help

Study Planning

Protocol: A - P00216 Schering No: 032089 Site Name: MORETASONE
 Country: NEVER NEVER LAND Plan Status: DRAFT Plan Version: 0

Protocol Projections Study Planning Site Initiations

Seq	Task ID	Planned Start D	Planned End D	Planned Min Delay	Actual Start D	Actual End D	Actual Max Delay	Actual Min Delay
1	P00216 - RNL	18-JUN-1998	18-JUN-1998	0	18-JUN-1998	18-JUN-1998	0	0
2	Protocol Number Assigned	18-JUN-1998	18-JUN-1998	0	18-JUN-1998	18-JUN-1998	0	0
3	Protocol Approved	00-0000	00-0000	0	00-0000	00-0000	0	0
4	Investigator Identified	00-0000	00-0000	0	00-0000	00-0000	0	0
5	Pre-Study visits Conducted	00-0000	00-0000	1	00-0000	00-0000	1	0
6	Last Pre-Study Visit Report C	00-0000	00-0000	0	00-0000	00-0000	0	0
7	First Site Initiated	00-0000	00-0000	0	00-0000	00-0000	0	0
8	First Subject First Visit	00-0000	00-0000	0	00-0000	00-0000	0	0
9	Enrollment Complete (Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
10	Last Subject/ Last Visit (Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
11	All Data In-house (Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
12	Database Locked	00-0000	00-0000	0	00-0000	00-0000	0	0
13	Primary Stat Analysis Results Re	00-0000	00-0000	0	00-0000	00-0000	0	0
14	Protocol Analysis Final	00-0000	00-0000	0	00-0000	00-0000	0	0
15	CSR Approved	00-0000	00-0000	0	00-0000	00-0000	0	0
16	(New)	00-0000	00-0000	1	00-0000	00-0000	0	0

Ready 6/18/98 11:15:05

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PROSIT - Never Never Land

File Edit View Actions Modules Forms Window Help

Study Planning

Protocol: P-P00124 Schering No: 000105 Schering Name: ESTRADOL

Country: NeverNever Land Plan Status: DRAFT Plan Version: 0

Study Planning Site Instructions Protocol Projections SMP Study Plan SMP Site Instructions

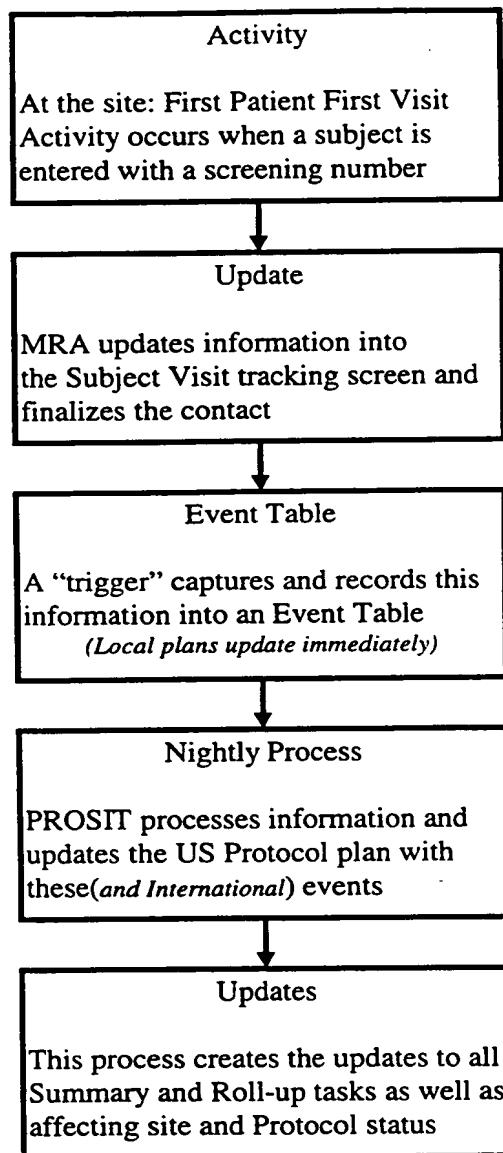
Seq	Task Name	Planned Start D	Planned End D	Planned Min Delay	Latest Start D	Latest End D	Latest Days	Latest Min Delay
1	P00124 - USA	12-AUG-1999	12-AUG-1999	0	12-AUG-1999	12-AUG-1999	0	
2	Protocol Number Assigned	12-AUG-1999	12-AUG-1999	0	12-AUG-1999	12-AUG-1999	0	
3	Final Protocol Date	00-0000	00-0000	0	00-0000	00-0000	0	0
4	Final CRF/RDE Screens Available	00-0000	00-0000	0	00-0000	00-0000	0	0
5	First Site Initiated	00-0000	00-0000	0	00-0000	00-0000	0	0
6	First Subject Enrolled(Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
7	First Subject, First Visit	00-0000	00-0000	0	00-0000	00-0000	0	0
8	Enrollment Cutoff (Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
9	Last Subject / Last Visit (Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
10	Last CIVE/Data Discrepancy In-H	00-0000	00-0000	0	00-0000	00-0000	0	0
11	Data Cleanup Complete (Protocol)	00-0000	00-0000	0	00-0000	00-0000	0	0
12	Database Locked	00-0000	00-0000	0	00-0000	00-0000	0	0
13	Primary Stat Analysis Results Re	00-0000	00-0000	5	00-0000	00-0000	5	0
14	Final Statistical Results Release	00-0000	00-0000	0	00-0000	00-0000	0	0
15	Final Data Listings Released	00-0000	00-0000	0	00-0000	00-0000	0	0

The country whose plan will be viewed and/or edited

12-AUG-1999

F 5. 25

THE EVENT MANAGER



Module: Event Manager

PROSIT driven for:
• Planned/Protocol Number Assigned

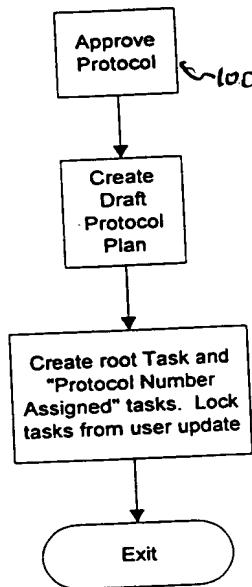


Fig. 27a

PROSIT driven for:
• Protocol Approved

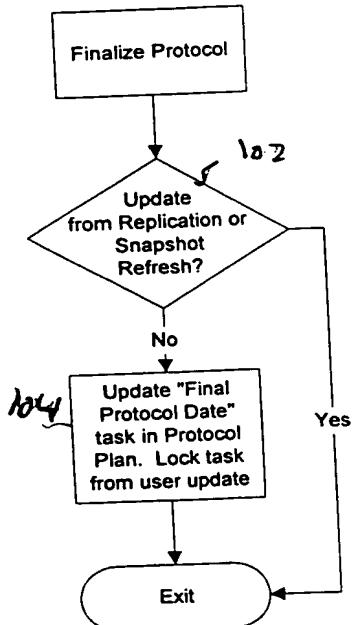


Fig. 27b

0955667-095600

Module: Event Manager

PROSIT driven for:

- Initiated/1st Site Initiated & Site Initiated

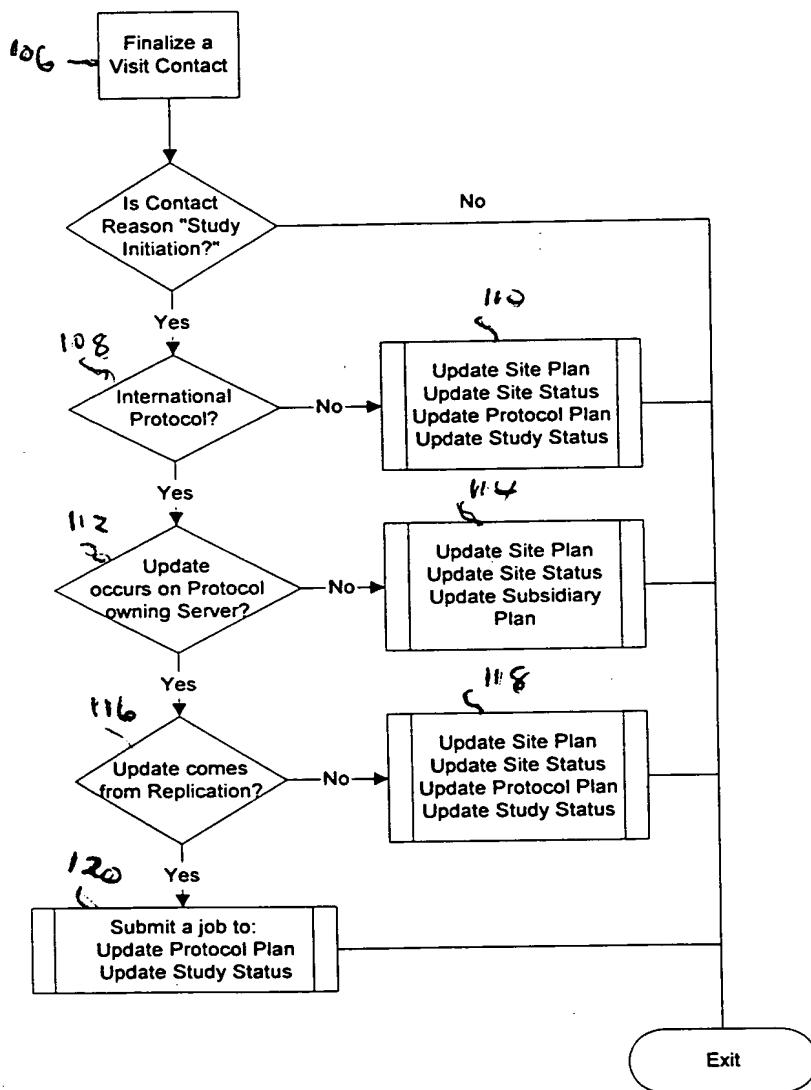
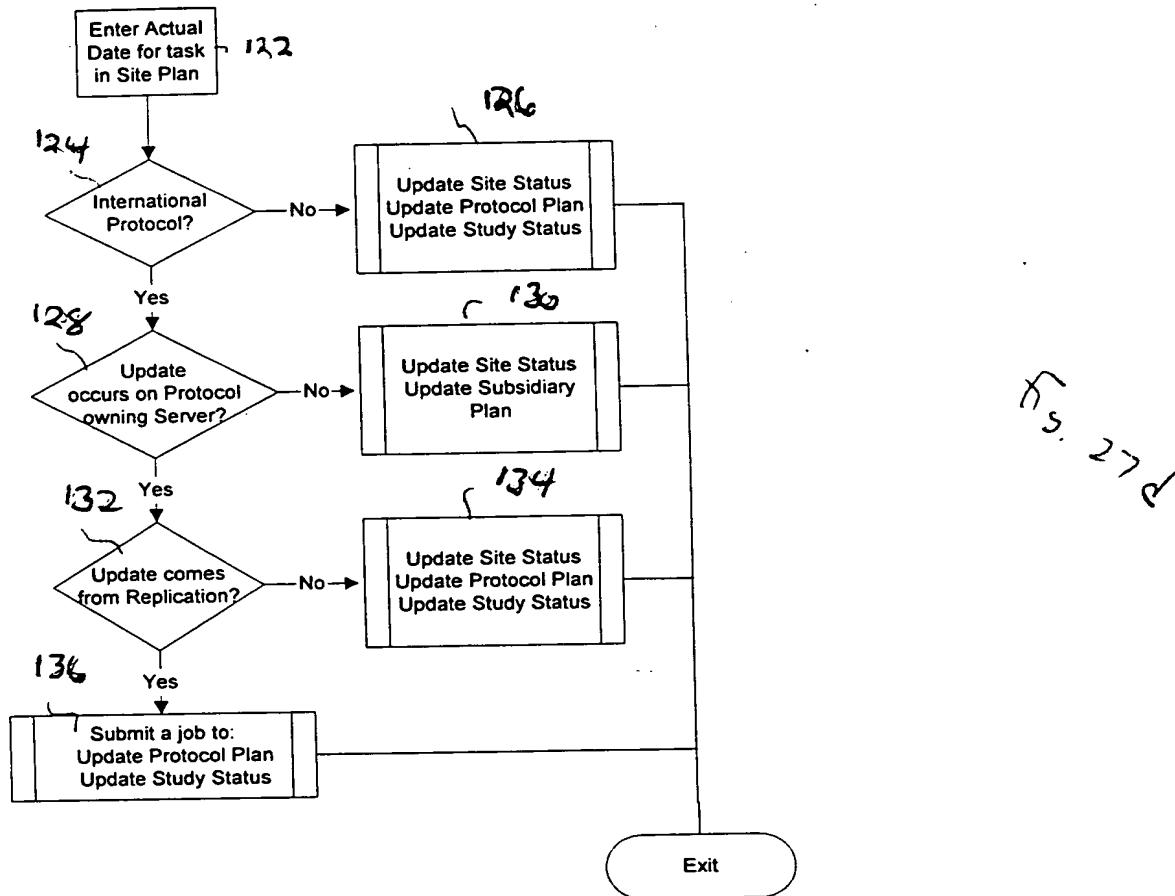


fig. 27c

Module: Event Manager

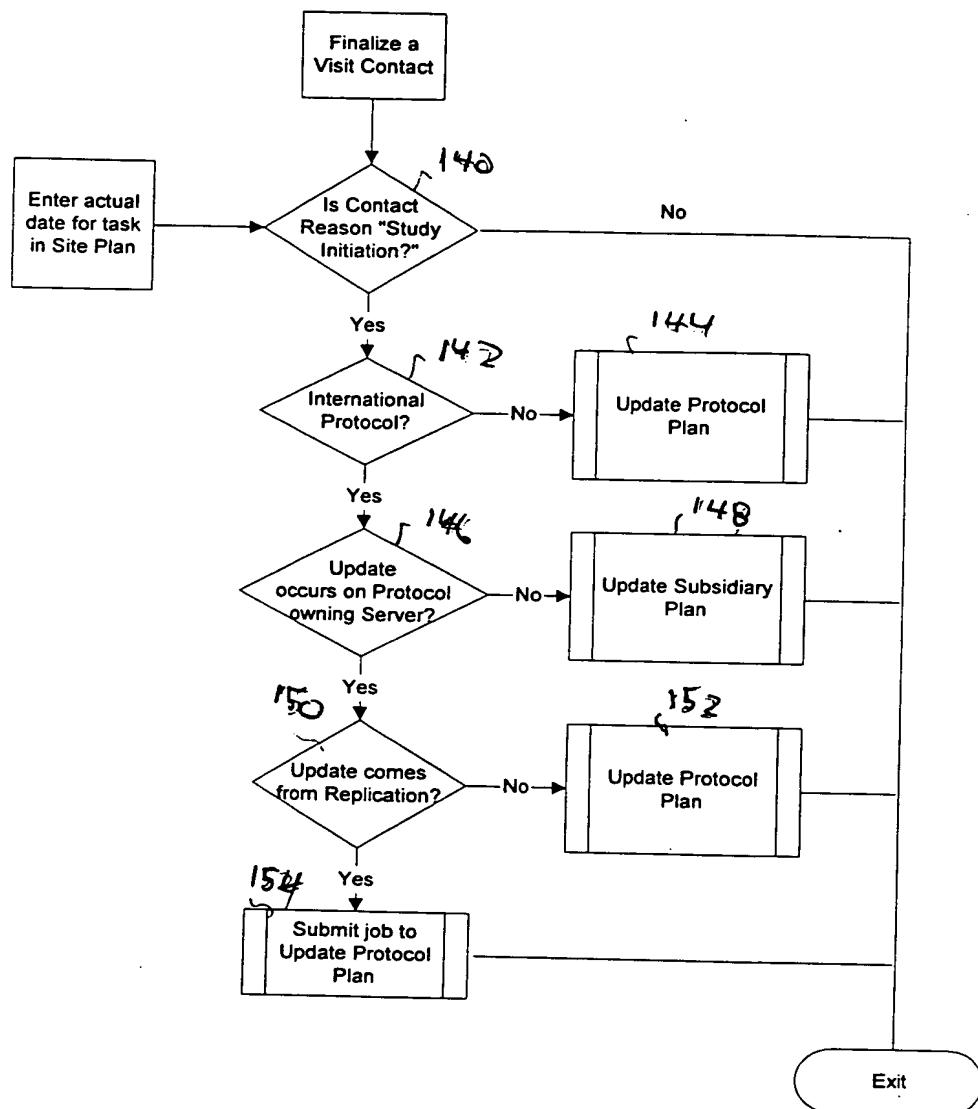
Milestone (site level) driven for:

- Initiated/1st Site Initiated & Site Initiated
- Screening Ongoing/First Subject, First Visit
- Enrollment Ongoing/First Subject Enrolled



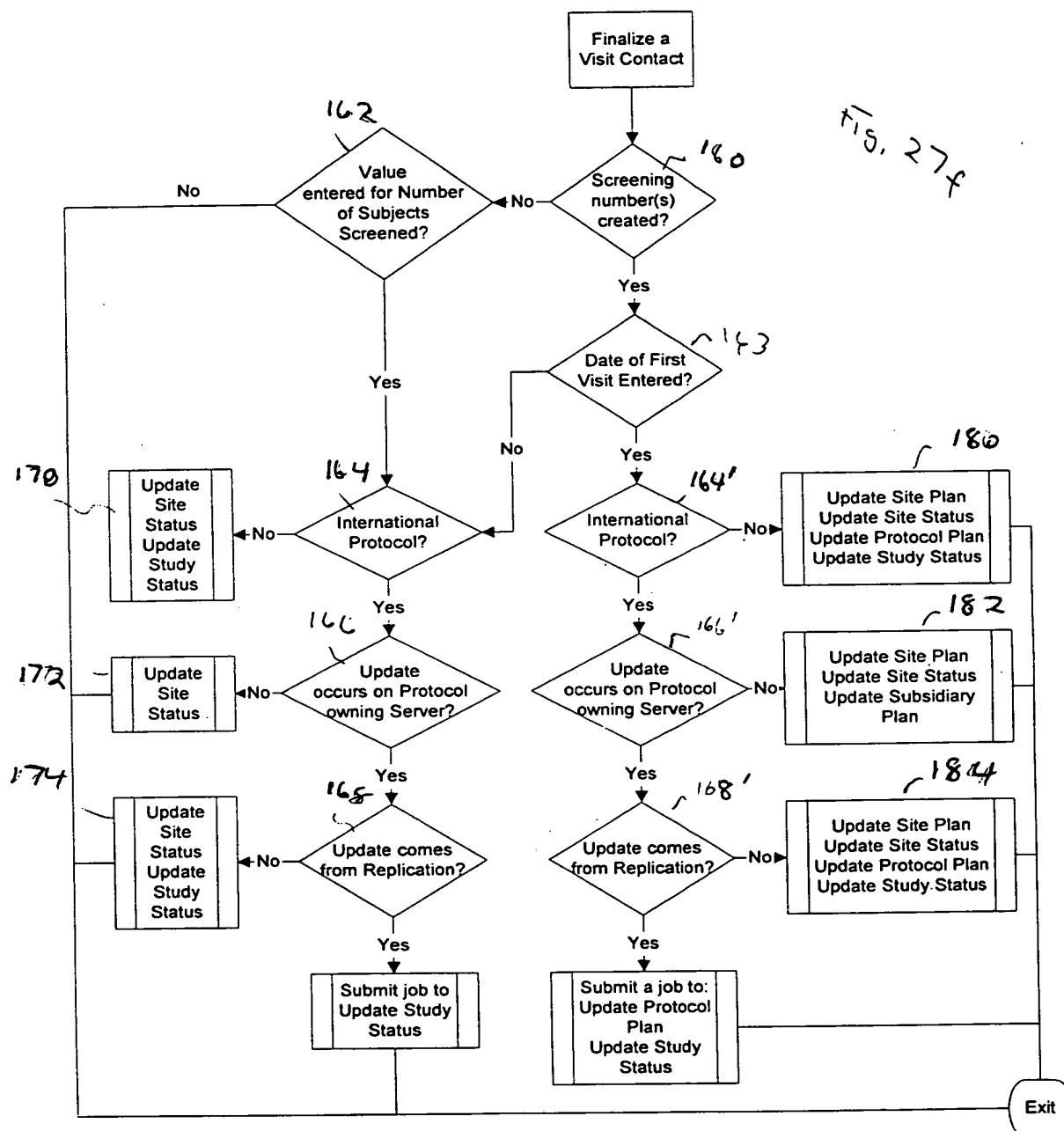
Module: Event Manager

PROSIT and Milestone driven for:
• Last Site Initiated (to Date)



Module: Event Manager

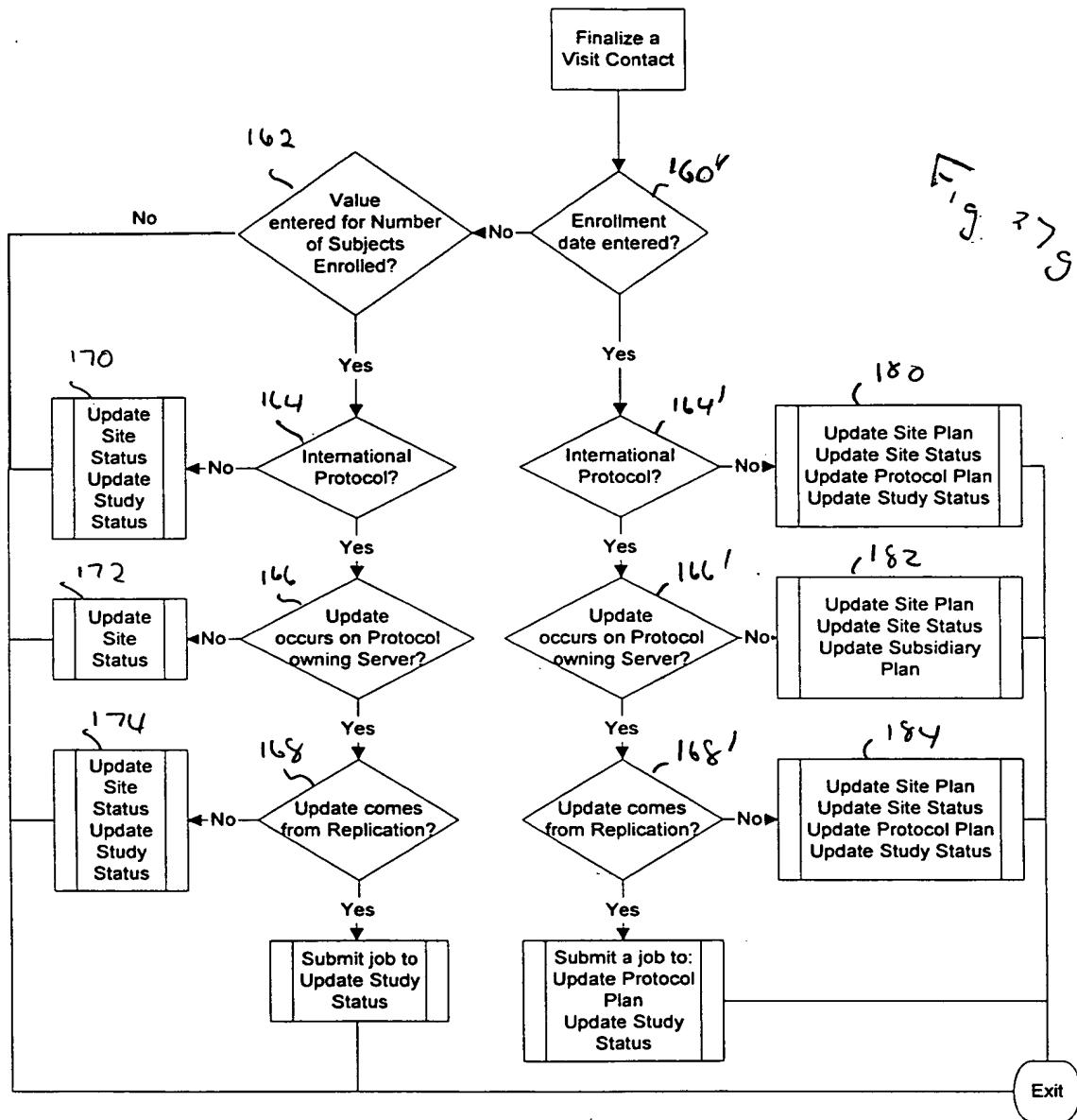
PROSIT driven for:
 • Screening Ongoing/First Subject, First Visit



Module: Event Manager

PROSIT driven for:

- Enrollment Ongoing/First Subject Enrolled



Module: Event Manager

Milestone (site level) driven for:

- Enrollment Complete
- Clinically Complete
- Site Closed

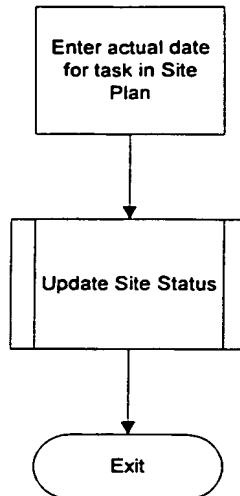
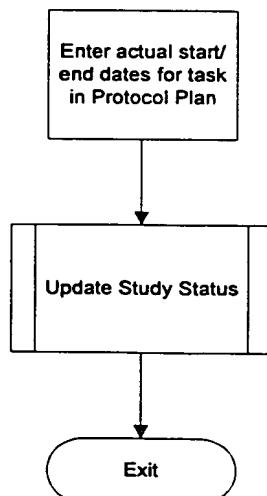


Fig. 27 h

Milestone (protocol level) driven for:

- Initiated/1st Site Initiated & Site Initiated
- Screening Ongoing/First Subject, First Visit
- Enrollment Ongoing/First Subject Enrolled
- Enrollment Complete
- Clinically Complete
- All Data In-House
- Data Cleanup Complete
- Database Locked
- CSR Approved



L.S. 27

PROSIT - Never Never Land

File Edit View Session Modules Window Help

Site Number Request

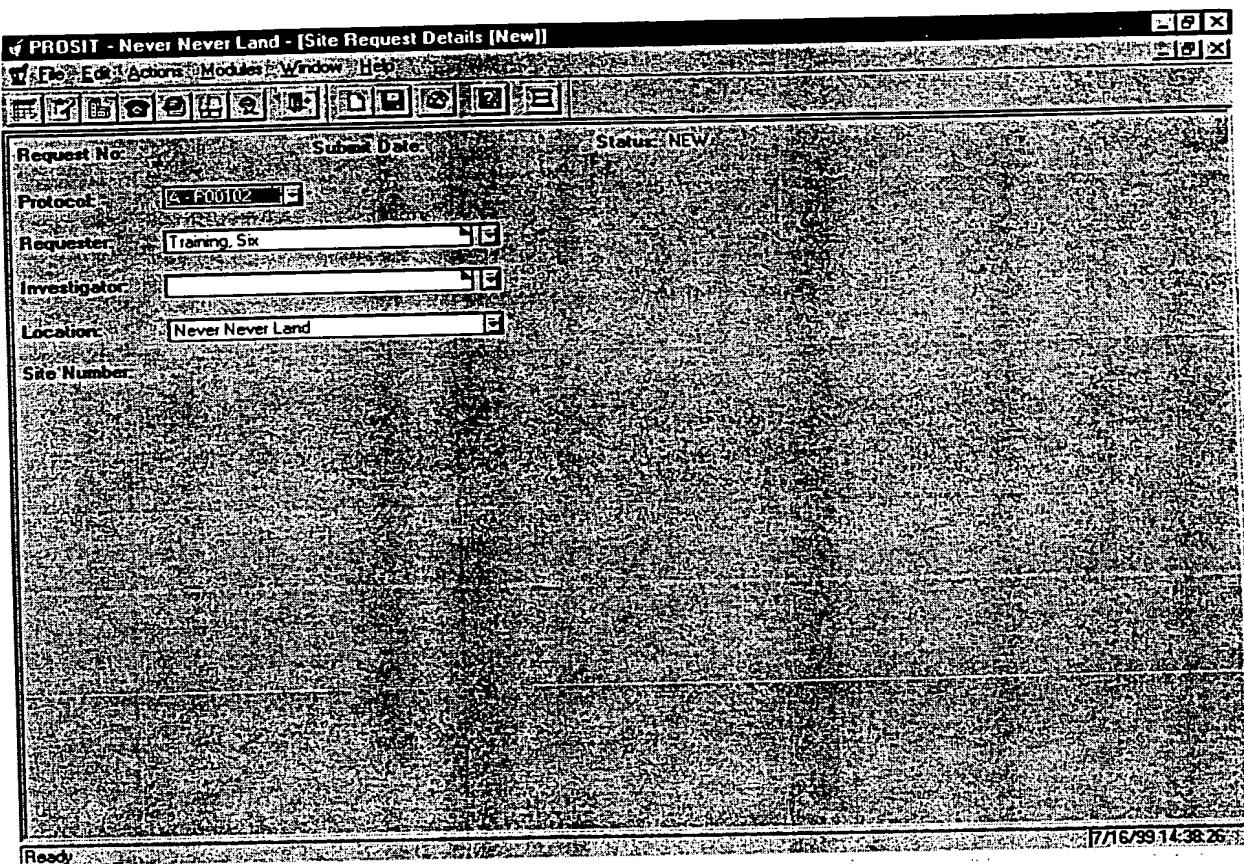
Request No	Submit date	Status	Site Country	Site Ref	Protocol	Site No	Requested	Investigator	Investigator
RQ - 10293	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	1	Training, One	Investigator, One	Never Never Land
RQ - 10294	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	2	Training, Two	Investigator, Two	Never Never Land
RQ - 10295	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	3	Training, Three	Investigator, Three	Never Never Land
RQ - 10296	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	4	Training, Four	Investigator, Four	Never Never Land
RQ - 10297	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	5	Training, Five	Investigator, Five	Never Never Land
RQ - 10298	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	6	Training, Six	Investigator, Six	Never Never Land
RQ - 10299	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	7	Training, Seven	Investigator, Seven	Never Never Land
RQ - 10300	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	8	Training, Eight	Investigator, Eight	Never Never Land
RQ - 10301	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	9	Training, Nine	Investigator, Nine	Never Never Land
RQ - 10302	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	10	Training, Ten	Investigator, Ten	Never Never Land
RQ - 10303	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	11	Training, Eleven	Investigator, Eleven	Never Never Land
RQ - 10304	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	12	Training, Twelve	Investigator, Twelve	Never Never Land
RQ - 10305	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	13	Training, Thirteen	Investigator, Thirteen	Never Never Land
RQ - 10306	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	14	Training, Fourteen	Investigator, Fourteen	Never Never Land
RQ - 11047	22-DEC-1998	RETURNED	Never Never Land	Q	P00041		Training, One	Hook, Captain	Never Never Land
RQ - 11048	22-DEC-1998	ASSIGNED	Never Never Land	Q	P00041	1	Training, One	Hook, Captain	Never Never Land
RQ - 11049	22-DEC-1998	ASSIGNED	Never Never Land	Q	P00041	2	Training, One	Bell, Tinker	Never Never Land
RQ - 11050	22-DEC-1998	RETURNED	Never Never Land	Q	P00041		Training, One	Investigator, Eight	Never Never Land
RQ - 11067	28-DEC-1998	RETURNED	Never Never Land	B	P00100		Training, One	Bell, Tinker	Never Never Land
RQ - 11068	28-DEC-1998	RETURNED	Never Never Land	A	P00102		Training, One	Bell, Tinker	Never Never Land
RQ - 11069	28-DEC-1998	RETURNED	Never Never Land	A	P00102		Training, One	Big Chief, Red	Never Never Land
RQ - 11070	28-DEC-1998	RETURNED	Never Never Land	A	P00102		Training, One	Bell, Tinker	Never Never Land
RQ - 11071	28-DEC-1998	ASSIGNED	Never Never Land	A	P00102	1	Training, One	Bell, Tinker	Never Never Land
RQ - 11072	28-DEC-1998	ASSIGNED	Never Never Land	A	P00102	2	Training, One	Big Chief, Red	Never Never Land

Ready

7/15/99 11:19:38

15, 28

Fig. 29



09655667 - 090600

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Site Administration

Protocol: I-P00324 Schering No: 000049
Site No: Investigator: Abduthay, G.

Schering Name: ANTERON
Country: UNITED STATES

Site Administration Post Study Eval.

Protocol
Study Status: PLANNED Notification: RESUME STUDY
Notification Reason:
Site Status: PLANNED Effective Amendment
Data Collection Tool: CRF Effective Date: 04-NOV-1998
Projected Enrollment
Req. Minimum: 0 Site Enrollment: 0
Prim. Location: YYYY
Pre-study Visit: Currency: U.S. DOLLARS

Name Function Phone Fax Local Inv. No
Abduthay, G. PRINCIPAL INVESTIGATOR

Ready 05-Jan-1999

Fig. 30

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Site Administration Post Study Eval.

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON
Site No: Investigator: Abdulhey, G Country: UNITED STATES

Global Assessment: NOT RECOMMENDED Evaluated By: Rispoli, Marc C
Evaluated On: 12-NOV-1998

ADEQUACY OF PATIENT SOURCE	GOOD	DRUG STORAGE AREA	ADEQUATE
FACILITIES	GOOD	LABORATORY	VERY GOOD
PRINCIPAL/CO-PRINCIPAL INVESTIGATOR	VERY GOOD	PFS TIME TO CONDUCT/SUPERV	VERY GOOD
STUDY STAFF	VERY GOOD	SUB INVESTIGATOR(S)	VERY GOOD

Ready 05-Jan-1999

Fig. 31

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Schering Name: ANTERON

Protocol: I-P00324 Schering No: 00009

Site No: Investigator: Abdulay, G. County: UNITED STATES

Locations | SP Personnel | Non SP Personnel | Non SP Personnel Locations

Active	Primary	Location	Role	Country	Address
<input checked="" type="checkbox"/>	<input type="checkbox"/>	HELSINKY YLIOPISTOLLINEN	(CO)SPONSOR	FINLAND	KESKUSAIPALA MEILAHDENTIE 2
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3V45_HSC_MCMASTER_UNIV	CENTRAL IR	CANADA	This is address line 1 for external organization printing 12345571
<input checked="" type="checkbox"/>	<input type="checkbox"/>	410-2000 CREDIT VALLEY RO	CONTRACT	CANADA	MISSISSAUGA
<input checked="" type="checkbox"/>	<input type="checkbox"/>	SCCOR, INC.	CENTRAL IR	UNITED STATES	8211 SCCOR DRIVE
<input checked="" type="checkbox"/>	<input type="checkbox"/>	kenilworth	CENTRAL IR	UNITED STATES	address
<input checked="" type="checkbox"/>	<input type="checkbox"/>	YYYY	CENTRAL LA	CANADA	YYYY
<input checked="" type="checkbox"/>	<input type="checkbox"/>				

Ready 05-Jan-1999

F 5. 32

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Site Personnel & Locations

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON
 Site No: [REDACTED] Investigator: Abdulhay, G Country: UNITED STATES

Locations: SP Personnel | Non SP Personnel | Non SP Personnel Locations

Active	Write	Employee	Responsibility	Active Date	Inactive Date	Country	Expense
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Ruspoli, Marc C	SITE REQUESTER	03-NOV-1998	00-0000	UNITED STATES	RESEARCH
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Lee, J.S.	CLINICAL DATA COORDINATOR	12-NOV-1998	00-0000	UNITED STATES	CHEM PR
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			05-JAN-1999	00-0000		

05-Jan-1999

Name of a site staff person from the Non SP Personnel tab

Fig. 33

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Site Personnel & Locations

Protocol: I-P00324 Sourcing No: 000049 Schering Name: ANTERON

Site No: Investigator: Abdulhay, G Country: UNITED STATES

Locations SP Personnel Non SP Personnel Non SP Personnel Locations

Active	Person	Responsibility	Active Date	Inactive Date	Country	Phone Number
<input checked="" type="checkbox"/>	Aepro, Mary S	PRINCIPAL INVESTIGATOR	03-NOV-1998	04-NOV-1998	UNITED STATES	908-603-3352
<input checked="" type="checkbox"/>	Aarons-You Ok, AL	DATA ENTRY CLERK/DATA COOR	04-NOV-1998	00-0000	US VIRGIN ISLANDS	vhgvbtkc0td k
<input checked="" type="checkbox"/>	Abdulhay, G	PRINCIPAL INVESTIGATOR	04-NOV-1998	00-0000	UNITED STATES	23243-12341234-1
<input checked="" type="checkbox"/>	Aaronson, AL	DIETICIAN	12-NOV-1998	00-0000	UNITED STATES	
<input checked="" type="checkbox"/>	Aaronson, D	HOSPITAL ADMINISTRATOR	12-NOV-1998	00-0000	UNITED STATES	
<input checked="" type="checkbox"/>	6565656, 67777 76	CONTRACT/GRANTS ADMINISTRATOR	12-NOV-1998	00-0000	AMERICAN SAMOA	
<input checked="" type="checkbox"/>	Abbeamont, T	IRB CHAIRMAN	12-NOV-1998	00-0000	UNITED STATES	1234
<input checked="" type="checkbox"/>			05-JAN-1999	00-0000		

Name of a site staff person from the Non SP Personnel tab:

05-Jan-1999

Fig. 34

09655667 090500

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Site Personnel & Locations

Protocol: I-P00324 Schering No.: 000049

Schering Name: ANTERON

Site No: 1 Investigator: Abduray, G

Country: UNITED STATES

Locations: SP Personnel Non SP Personnel Non SP Personnel Locations

Associated Site Personnel: Aaronson, D

Primary Location	Role	Country	Address
<input checked="" type="checkbox"/> SCICOR, INC.	CENTRAL IRB/EC	USA	6211 SCICOR DRIVE
<input type="checkbox"/> YYYY	CENTRAL LABORATORY	CAN	YYYY
<input type="checkbox"/> 410-2000 CREDIT VALLEY	CONTRACT RESEARCH ORGANIZATION	CAN	MISSISSAUGA
<input type="checkbox"/> 3M45 HSC MCMASTER	CENTRAL IRB/EC	CAN	This is address line 1 for external organization printing 1234567, HAI
<input checked="" type="checkbox"/> HELSINGIN YLIOPISTO	(CO)SPONSORING ORGANIZATION	FIN	KESKUSSAIRALA MELAHENTIE 2
<input type="checkbox"/> kenworth	CENTRAL IRB/EC	USA	002
<input type="checkbox"/>			address
<input type="checkbox"/>			city

A check indicates that this is the primary location for contacting this site staff person

05-Jan-1999

Fig. 35

09255667 0906000

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Site Study Tracking

Protocol: I-PO0324 Schering No: 00049 Schering Name: ANTERON

Country: UNITED STATES Site: 1 Investigator: Abdulhay, G

Seq #	Task Name	Lastest Date	Actual Date
1	IP00324-USA	00-0000	02-NOV-1998
2	Completed Grant Request Form Received in Sub.	00-0000	00-0000
3	CV of Laboratory Director(s) Received in S	00-0000	00-0000
4	Budget Info Sheet (signed&dated by Inv.) Rec	00-0000	00-0000
5	CV of Laboratory Director(s) Received in Sub.	00-0000	00-0000
6	CV of Laboratory Director(s) Sent to HO	00-0000	00-0000
7	Completed Grant Request Form Sent to HO.	00-0000	00-0000
8	Curriculum Vitae of Principal Inv.(s) Rec. in	00-0000	00-0000
9	Curriculum Vitae of Principal Investigator(s)	00-0000	00-0000
10	Curriculum Vitae of Sub-inv.(s) Received in S	00-0000	00-0000
11	Curriculum Vitae of Subinvestigator(s) Sent	00-0000	00-0000
12	Doc. of Quality Control Proc. or Cert. Rec. in	00-0000	00-0000
13	Doc. of Quality Control Proc. or Cert. Sent to	00-0000	00-0000
14	FDA Form 1572 Received in Sub.	00-0000	00-0000
15	FDA Form 1572 Sent to HO.	00-0000	00-0000
16	Gov. Regulatory App. (w/ trans.) Sent to HO.	00-0000	00-0000
17	Gov. Regulatory App. (w/trans.) Received in S	00-0000	00-0000
18	Informed Consent Task(Trans)	00-0000	00-0000
19	Informed Consent Doc. (with translation) Sent	00-0000	00-0000
20	Site Closed	00-0000	00-0000

The site whose tracking will be viewed/edited

05-Jan-1999

F 5. 36

00655662 0065600

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Site Budget

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON
Site No: Investigator: Abdulhay, G Currency: U.S.DOLLARS Revision:

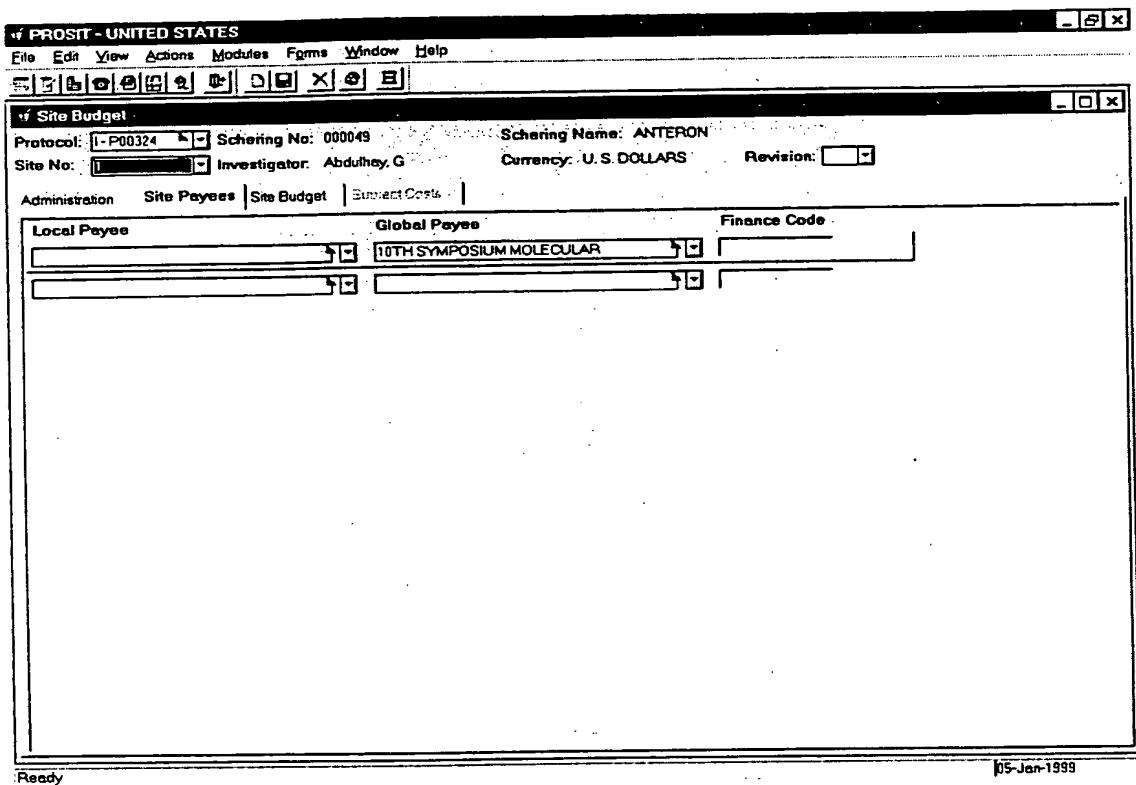
Administration Site Payees Site Budget Subject Costs

Status:
Amendment:
Submit Date: 00-0000
Effective Date: 00-0000
Overhead Percent: 0.00

The label that identifies the name of the visit schedule selected. Procedures for the discontinuation visit are also budgeted here

05-Jan-1999

Fig. 37



Fs. 38

PROSIT - Never Never Land

File Edit View Actions Modules Forms Window Help

Site Budget

Protocol: A-P00102 Schering No: 000001 Schering Name: STEROIDS FOR SKIN TESTS
 Site No: 4 Investigator: Big Chid. Red Currency: GOURDE Revision: 1

Administration Site Payees Site Budget Subject Costs

Protocol: P00102 Site No. 4 Revision: 1N REVISION Effective Date: Amendment:

Line Item	OH Default Payee	Unit Cost	Units	Total
SUBJECT COSTS				
PROCEDURE COSTS				
Laboratory Evaluation	<input checked="" type="checkbox"/> Captain Hook	10.00	5	50.00
Medical History	<input checked="" type="checkbox"/>	100.00	2	200.00
	<input type="checkbox"/>	.00		
ADDITIONAL VISIT COSTS				
Evaluation	<input checked="" type="checkbox"/> 10TH SYMPOSIL	100.00	3	300.00
	<input type="checkbox"/>	.00		
ADJUSTMENTS				
Recovery	<input type="checkbox"/>	100.00	2	200.00
	<input type="checkbox"/>	.00		
OTHER COSTS				
Advertisement	<input checked="" type="checkbox"/> 10TH SYMPOSIL	100.00	2	200.00
Discovery	<input checked="" type="checkbox"/> Captain Hook	20.00	3	60.00
TOTAL BUDGET 1,060.00				
PREVIOUSLY APPROVED				
REQUIRED				

A description of the line item cost

12-Aug-1999

Fig. 39

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Site Budget

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON
 Site No: 1 Investigator: Abdutay, G. Currency: U.S.DOLLARS Revision:

Administration Site Payees Site Budget Subject Costs

Treatment Schedule: Treatment Schedule 1

Line Item	Subjects Budgeted >	Visit # >		
		1	2	3
13C-UREA BREATH TEST		\$0.00	\$0.00	\$0.00
12-LEAD ECG		\$0.00	\$0.00	\$0.00
2-VIEW XRAY		\$0.00	\$0.00	\$0.00
24-HOUR URINE COLLECTION		\$0.00	\$0.00	\$0.00
4-VIEW XRAY		\$0.00	\$0.00	\$0.00

Ready 05-Jan-1999

Fig. 40

00000000000000000000000000000000

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Pre-Study Visit

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Pre-Study Visit No: 10566 Principal Investigator: Aasebo, U Country: NORWAY

Pre-Study Visit SP Personnel NSP Personnel Discussion Items Evaluation

Potential Investigator: Aasebo, U Potential Study Location: Location Name

Country: AFGHANISTAN

Visit Date: 18-NOV-1998 Time: 16:25 Finalized: 00:0000

Schering Participants: Investigator Site Participants: Non-Registered()

Rispol, Marc C Aasebo, U

Ready 05-Jan-1999

F5. 41

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Pre-Study Visit

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Pre-Study Visit No: 10566 Principal Investigator: Aslebø U Country: NORWAY

Pre-Study Visit SP Personnel NSP Personnel Discussion Items Evaluation

Registered Site Personnel - Title

Kasebo U

Nos - Registered Site Personnel

Last Name: First Name: Title:

This is a registered site person

DS-Jan-1999

Fig. 42

09555557 - 090600

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Pre-Study Visit

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Pre-Study Visit No: 10566 Principal Investigator: Aasebo, U Country: NORWAY

Pre-Study Visit SP Personnel NSP Personnel Discussion Items Evaluation

STUDY CONSIDERATIONS

- Pre Clinical Data
- Clinical Data
- Investigator Brochure
- Protocol
- Case Report Forms
- Monitoring Responsibilities
- Study Schedule
- Principal Investigator Responsibilities
- Sub-Investigator Responsibilities
- Staff Responsibilities
- Grant
- Payment Schedule

ETHICAL CONSIDERATIONS

- Curriculum Vitae
- Principal Investigator
- Co-Principal Investigator
- Sub-Investigator
- Lab Director
- Laboratory Certification
- Laboratory Q.C. Procedures
- Laboratory Performance Ranges
- DEA Regulations and Drug Control
- Adequacy and Accuracy of Records
- Availability of Patient Records
- Drug Accountability and Disposition
- IRB/EC
- Approval Documents
- Responsibilities
- Retention of Records
- Informed Consent
- FDA 1572 OR
- Investigator Agreement
- Nature of FDA Inspection

Ready 05-Jan-1995

Fig. 43

PROSIT - UNITED STATES

File - Edit - Actions - Modules - Forms - Window - Help

Pre-Study Visit

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Pre-Study Visit No: 10586 Principal Investigator: Aasbo, U Country: NORWAY

Pre-Study Visit | SP Personnel | NSP Personnel | Discussion Items | Evaluation |

Global Assessment: RECOMMENDED

ADEQUACY OF PATIENT SOURCE: GOOD DRUG STORAGE AREA:
FACILITIES: LABORATORY:
PRINCIPAL INVESTIGATOR/CO-PRIN: PTS TIME TO CONDUCT/SUPERVISE: VERY GOOD
STUDY STAFF: SUB INVESTIGATORS:

Ready 05-Jan-1999

Fig. 44

PROSIT - UNITED STATES

File Edit Tools Actions Modules Forms Window Help

Visit Contact

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Site No: Contact: 00011266 - 04-Nov-1998 uninitialized

Contact Information

Originator: Rispoll, Marc C Reason: CLINICAL STUDY SUPPLIES

Date: 04-NOV-1998 Time: 00:00

Meeting Location

Site Roster: Testing the new prosit 1.03.1 build
 Other:

The investigator site is:

Recommended
 Not Recommended

Schering Participants

Rispoll, Marc C

Non-Schering Participants

Aspro, Mary S

The study center that was involved in this contact

05-Jan-1999

Fig. 45

PROSIT - Never Never Land

File Edit Tools Actions Modules Forms Window Help

Protocol: P00036 Schering No: 032088 Schering Name: MOMETASONE

Site No: 4 Contact: 00008480 - 02-Aug-1999 finalized

Electronic Mail Contact | Discussion Items

Contact Information

Originator: Dating, John Reason: ADVERSE EVENT

Date: 02-AUG-1999 Time: 10:01

Phone Contact Details

Outside Party Phone #: 555-555-5555

Schering Participants

But, Thud

Non-Schering Participants

03-Aug-1999

Ready

F15, 46

PROSIT - UNITED STATES

File Edit Tools Actions Modules Forms Window Help

Visit Contact

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Site No: 00011286 Contact: 00011286 - 04-Nov-1998 unfinished

Visit Contact Discussion Items

<p>New Pre-Clinical or Clinical Data</p> <p><input type="checkbox"/> Efficacy</p> <p><input type="checkbox"/> Adverse Events</p> <p>Protocol Adherence</p> <p><input type="checkbox"/> Subject Selection</p> <p><input type="checkbox"/> Conduct Of Study</p> <p><input type="checkbox"/> Adverse Events</p> <p><input type="checkbox"/> Concomitant Medications</p> <p>Case Report Form (CRF) Records</p> <p><input type="checkbox"/> CRF Completion vs. Patient Enrollment</p> <p><input type="checkbox"/> CRF Completeness</p> <p><input type="checkbox"/> CRF Availability, Storage and Retention</p>	<p>Personnel Responsibilities</p> <p><input type="checkbox"/> Principal Investigator</p> <p><input type="checkbox"/> Sub-Investigator</p> <p><input type="checkbox"/> Staff</p> <p>Facilities</p> <p><input type="checkbox"/> Location Of Patient Info.</p> <p><input type="checkbox"/> Clinical Laboratory</p> <p><input type="checkbox"/> Equipment</p> <p><input type="checkbox"/> Other</p>	<p>Clinical Supplies</p> <p><input type="checkbox"/> Quantity</p> <p><input type="checkbox"/> Storage</p> <p><input type="checkbox"/> Dispensing</p> <p><input type="checkbox"/> Packaging/Labeling/Coding</p> <p><input type="checkbox"/> Randomization</p> <p><input type="checkbox"/> Recertification Date</p> <p><input type="checkbox"/> Drug Disclosure Envelopes</p> <p><input type="checkbox"/> Documentation of Accountability</p>	<p>Monitoring Activities</p> <ul style="list-style-type: none"> <input type="checkbox"/> Action Taken By PI and Monitor to correct deficiency <input type="checkbox"/> Source Document Verification Completed <input type="checkbox"/> Consents Reviewed <input type="checkbox"/> Source Document Checked
---	---	---	---

* Required to finalize the site contact.

The study center that was involved in this contact:

0965662 090500

05-Jan-1999

1-15.47

PROSIT - UNITED STATES

File Tools Actions Modules Window Help

Site Tracking

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Site: 1 Contact: 11286 Visit: Unfinalized As of: 03-Nov-1998

Enrollment Tracking | Ineligible For Screening

	Enrollment as of Unfinalized Site Visit	Enrollment as of Latest Finalized Visit
Potential Subjects Ineligible for Screening:	2	0
Number of Subjects Screened:	10	0
Number of Subjects Failed Screening:	2	0
Number of Subjects Enrolled:	8	0
Number of Subjects Discontinued total:	2	0
Adverse Events:	1	0
Other:	1	0
Number of Subjects Complete:	5	0
Number of Subjects Ongoing:	1	0

Ready 05-Jan-1999

Figs. 48a

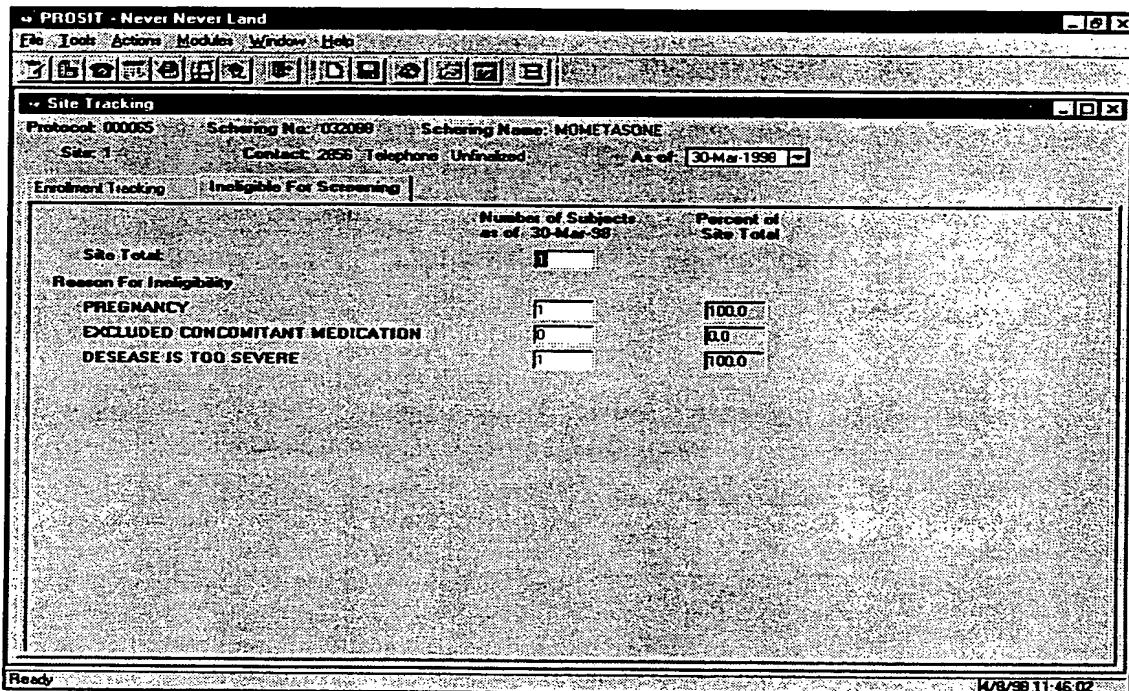


Fig. 4E6

09655662 0960600

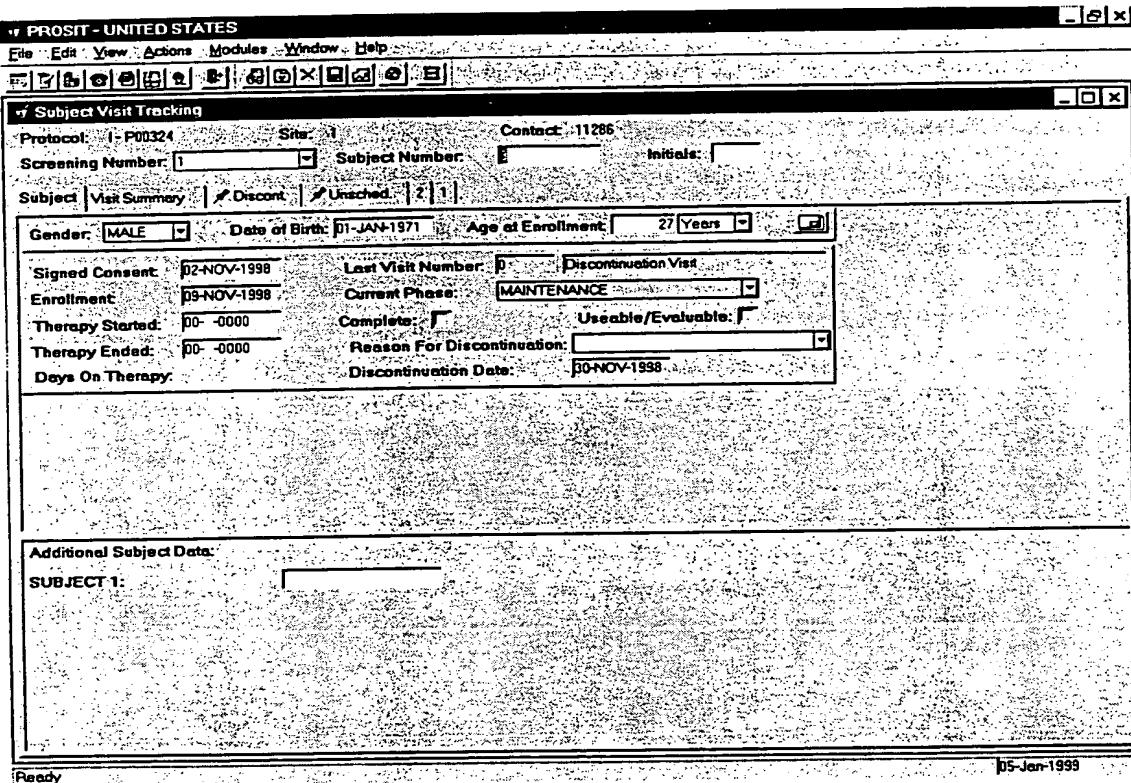


Fig. 49

09656667 090600

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Subject Visit Tracking

Protocol: I-P00324 Site: Contact: 11286

Screening Number: Subject Number: Initials:

Subject Visit Summary Discom Unsched 2 1

Visit No	Amendment	Visit Label	Visit Date	Delta	TO DO	CRF Status	SDV Status
1		Visit 1	09-Nov-1998		<input type="checkbox"/>	COLLECTED	<100%
2		Visit 2	16-Nov-1998	6	<input type="checkbox"/>	PARTIALLY COLLECTED	<100%
3		Unscheduled Visit	23-Nov-1998		<input type="checkbox"/>	PARTIALLY COLLECTED	
4		Discontinuation Visit	30-Nov-1998		<input type="checkbox"/>	NOT COLLECTED	

Ready 05-Jan-1999

Fig. 50

00000000000000000000000000000000

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Formulated Materials Requisition

FMR Req. ID: 184

Administration Materials

Protocol Information

Protocol Number: A-F00240 Schering No: 000026 A AND D

Program Code: F05 Schering No: 000026 Dose Form: BOLUS

Expense Center: 1495 - WORLDWIDE RSCH OA

Requisition Source: ANIMAL HEALTH DOMESTIC/INTERNATIONAL

Requested by: Desontos, Marc

Authorized by: Desontos, Marc

Date Required For Packaging: 22-DEC-1998 Blinding Required:

Special Directions and Blinding (explain blinding requirements if any):

A protocol under which the requested supplies will be utilized

05-Jan-1999

Fig. 51

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

PSR Request Protocol Packaging

Protocol: I-P00324 Schering No:000049 Schering Name: ANTERON
Country: UNITED STATES PSR No: 1409

PSR Information | Components | Ship To |

Project Accounting Code: F01-000049-303E Exp Center: 1477 RESEARCH SYS

New Protocol/Site: Study Type: Blind Open

Study Monitor: Grint PC

Random Code Format: CODE ENVELOPES

Requested by: Ruspilli, Marc C

Authorized by: 3,3

Required Ship Date: 31-MAR-1999 Random Code Generation ID: Select Sites

IND Labeling Date: 00-0000

Special Instructions:

Attachments: PROTOCOL LABEL FORMAT LABELING INSTRUCTIONS DEA FORM 222C CONFIRMATION DEA REG. N

A number generated when the PSR is first saved to uniquely identify the PSR. This is not the PSR number generated by the clinic. 05-Jan-1999

Fig. 52

09655662 * 090600

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

PSR Request: Protocol Packaging

Protocol: C-C98005 Schering No: 032088 Schering Name: MOMETASONE

Country: UNITED STATES PSR No: 1010

PSR Information Components Ship To

Schering No.	Schering Name	Test Dose Form	Strength/ concentration	Package Description/Fill	Required Units
032088	MOMETASONE	ORAL AERPR	UNKNOWN		

The Schering number of the drug that will be packaged. 10.2.1999

Fig. 53

09655662 090600

PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

PSR Request: Protocol Packaging

Protocol: I-P00324 Schering No:000049 Schering No: ANTERON

Country: UNITED STATES PSR No: 1489

PSR Information Components Skip To:

Location: SCHERING CANADA INC

Address: 170 ONEIDA STREET

City: POINTE CLAIRE US State/Other:

Postal Code: H9R 1B4 Country: CANADA

Phone: 514 426 7300

Fax: 514 426 7300

Attention:

The subsidiary to which the clinical supplies will be shipped.

05-Jan-1999

Fig. 54

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PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Material Transfer Request

Protocol: C-P98615 Schering No: 034117 Schering Name: DESLORATADINE

Country: UNITED STATES Site No: 1 MTR No:

MTR Details Ship To:

Inventory Location: Requested Ship Date: 00-0000

Requested By: Caprio, Denise M

Authorized By: Intended Use Of Material:

Expense Center: 1751 SR DIR INTL CLN RES

Material Type Batch No. PSR No. FMR No. Quantity Quantity On Hand

The type of material to be shipped.

14-Jun-1999

FIS, 55

RT

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PROSIT - UNITED STATES

File Edit View Actions Modules Forms Window Help

Material Transfer Request

Protocol: C-P98615 Schering No: 034117 Schering Name: DESLORATADINE

Country: UNITED STATES Site No: 1 MTR No: AA000637

MTR Details: Ship To:

Location:
Address:
City: State/Province:
Postal Code: Country:
Phone: Fax:
Attention:
Shipping/Packaging Instructions:

The name of the person who will receive the shipment at this location:

Fig. 56

09655660-0965600

PROSIT - UNITED STATES

File Edit Actions Modules Forms Window Help

Random Code Request - New

Protocol: Q-P00759 Schering No: 032088 Schering Name: MOMETASONE
Random Code Req ID: Date Prepared: 00-0000 Pctl Finalization Dt: 21-JUL-1999

To: Copies:
From: Caprio, Denise M
Random Code Type:
Generate Random Code by: 00-0000

Number of United States Sites: 2 First United States Site ID: Comments:
Number of International Sites: First International Site ID:
Subj: Randomized by:
Subj: Replaced by:
Subj nbr assigned by:
Number of Stratification:

Treatment Arm Subjects
Total Subjects: 0

A number generated when the RCR is first saved to identify the random code request memo.

11-Aug-1999

Fig. 57

09655662 090500

PROSIT - UNITED STATES

File Actions Modules Window Help

Check Control

Userid: RENOWSKIG Renowski, George

Check Out

Date: 13-Jul-1999 Extra Items Status: Checked out data available

Protocol	Site	Primary Location	Site Investigator	Site Requester
B93214		No Site - Pcl only		
B94055		No Site - Pcl only		
B94056		No Site - Pcl only		

Request Date Status Check In Date Checked In Date Reply from server

The logon ID of the user whose status is being requested 12-Aug-1999

Fig. 58

SUBJECT DETAIL REPORT

PROSIT - NEVER NEVER LAND

File Edit View Actions Modules Window Help

Subject Detail Report

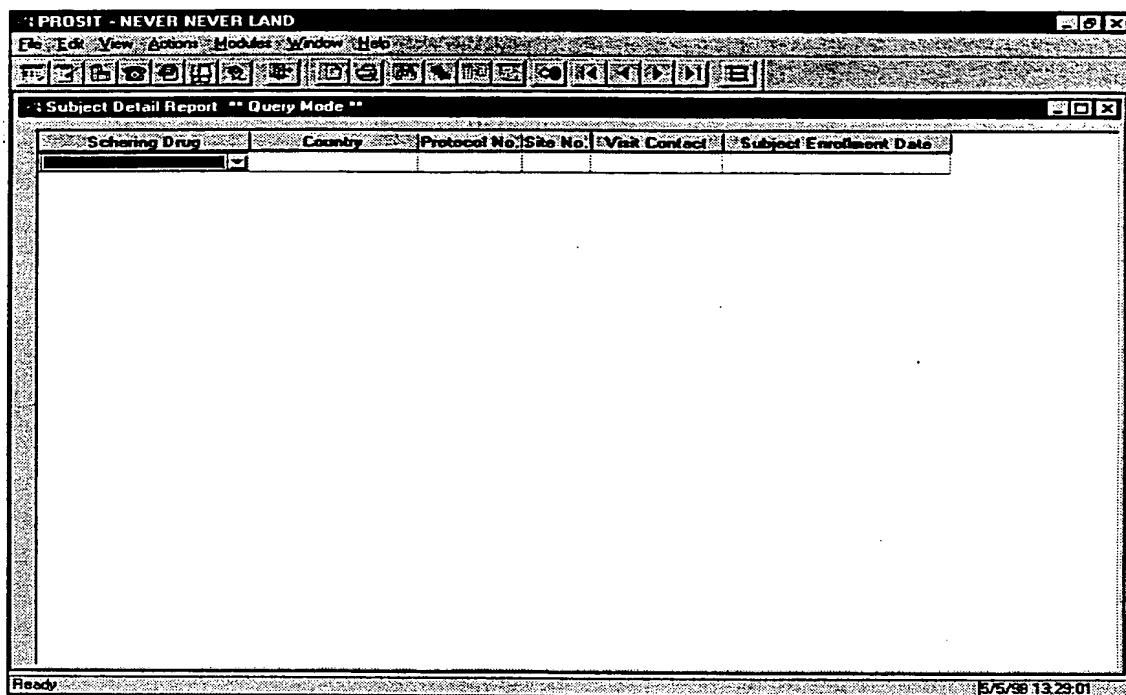
PROSIT - SUBJECT DETAIL REPORT				
Schering No.	032088 MOMETASONE	Working Study Title	Protocol No. - Site No.	
Principal Investigator	Daniel W AARONSON, M.D.	retesting the 110 visit map id st	H000017-	
Study Location		fhdghdghdghdghdghdthdthdf, UNITED STATES		
Monitor				
SUBJECT: 6001AKM/1				
Gender:	M	Last Visit Date:	09-APR-1998	
Age:	30 years	Last Visit Label:	Visit 3	
Date of Birth:	07-AUG-1967	Tx Started:		
Signed Consent:		Tx Stopped:		
Evaluable:		Days on Tx (to date):		
Reason for Discontinuation				
As Of: 05-Mar-1998 Contact ID : 6038				
Visit	Date (DoR)	SDV	CRF Status	Pages Collected
Screening	05-MAR-1998 (0)	100%	COLLECTED	
Visit 1	12-MAR-1998 (5)		COLLECTED	
Visit 2	26-MAR-1998 (12)	100%	COLLECTED	
Visit 3	09-APR-1998 (12)	100%	COLLECTED	
SUBJECT: 6002KG/2				
Gender:	F	Last Visit Date:	09-APR-1998	Reason for Discontinuation
Age:		Last Visit Label:		DEATH
Date of Birth:	28-JUL-1969	Tx Started:		

5/5/98 13:27:45

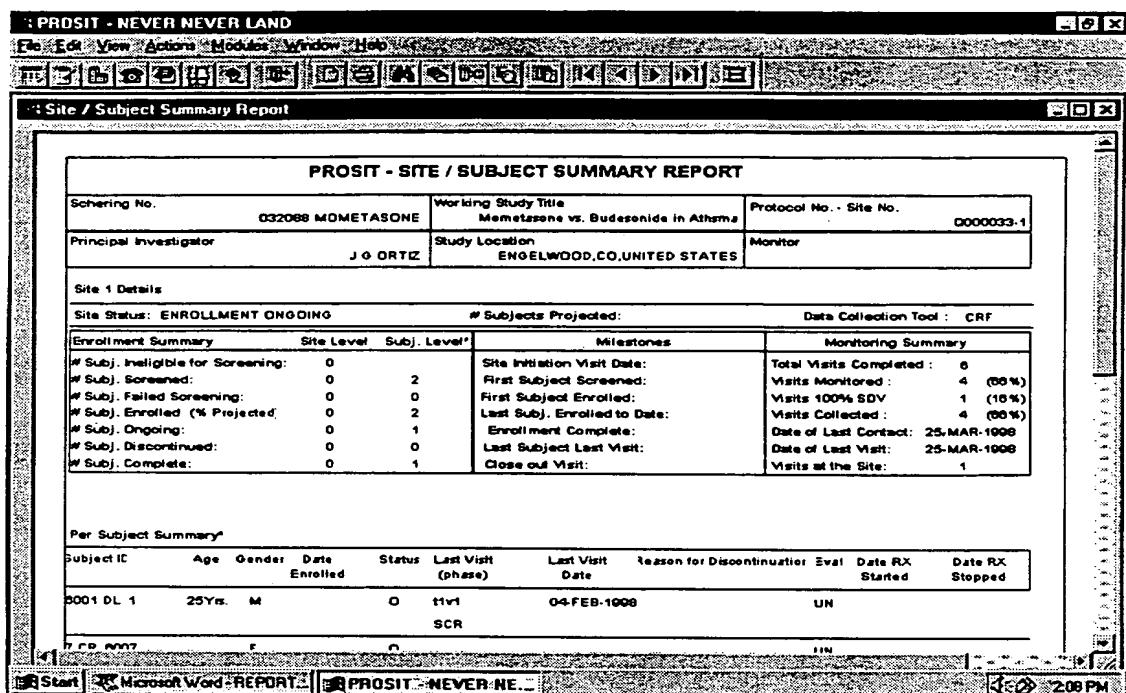
Ready

15.59

QUERYING



SUBJECT SUMMARY REPORT



MONITORING STATUS REPORT

PROSIT - NEVER NEVER LAND

File Edit View Actions Modules Window Help

: Monitoring Status Report

PROSIT - MONITORING STATUS REPORT

Enrolment No.	00000000000000000000000000000000	Working Title	Monotherapy vs. Butenafine in Atopic Dermatitis	Protocol No./Site No.	000000-1
Principal Investigator	J GORTIZ	Study Location	ENGLEWOOD CO/UNITED STATES	Monitors	

Site 1 Summary

As Of: 25-Mar-1998 Site Contact No: 2626

Status	Visits	Subjects
Present: AMENDED	Completed: 0	Projected: 0
Site: ENROLLMENT ONGOING	Non-Initial: 0 (0%)	Actual & Forecasted: 2
Visits at the site: 4	100% SDV: 1 (100%)	Actual & Forecasted: 1
Date of last visit: 28-Mar-1998	Collected: 4 (100%)	Actual & Completed: 1

Site 1 Details

Subject	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13	V14	V15	D/C Status
600V011	100	100	100	100												
70C84007	C				C											
Completed	2	1	1	1	0	0	1	0	0	0	0	0	0	0	0	
Non-Initial	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	
Collected	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	

Legend: C = Completed; 100 = 100% SDV; KU = Key Usability; <100 = <100% SDV; || = Collected/needed = Discontinued
V1 = test recruitment; V2 = baseline; V3 = (V1; V4 = (V2; V5 = (V3; V6 = (V4; V7 = screen V2

Ready 5/5/98 14:36:01

F 5. 62

096556537 - 0906000

SITE PERSONNEL AND LOCATION REPORT

PROSIT - Never Never Land

File Edit View Actions Modules Window Help

Site Personnel & Locations Information Report

PROSIT - SITE PERSONNEL & LOCATIONS INFORMATION SHEET

Schering No.	032088 MOMETASONE	Working Title	Mom vs Dad in Asthma
Protocol No.	AP00045-1	Expense Center	1763 - CLINICAL RESEARCH - ALLERGY II
Principal Investigator	J TABASCOMINGUILLAN	Monitoring Country	Never Never Land

NON SP PERSONNEL

Maid, Mer	Tabascominguillan, J	Bell, Tinker
IRB CHAIRMAN	PRINCIPAL INVESTIGATOR	STUDY COORDINATOR
NNL	NNL	NNL
Active: 22-Apr-1998	Active: 22-Apr-1998	Active: 22-Apr-1998

CENTRAL IRB/EC

MERMAID ROCK
2 Stone Skip
NNL

TREATMENT CENTER

PIRATE SHIP
Out at Sea

Next: 6/18/98 14:07:04

F, S. 63

02655667 026600

CONTACT INFORMATION REPORT

PROSIT - UNITED STATES

File Edit View Actions Modules Window Help

Contact Information Report

PROSIT - CONTACT INFORMATION SHEET

Schering No.	000058 NIACIN	Working Title	domestic
Protocol No.	A000001		

PROTOCOL A000001 EXTERNAL ORGANIZATIONS

CENTRE UNIVERSITAIRE DE SANTE	61200	National Genetics Institute
Gunn, Mark C	Aarons, A L	Kadmon, D
DE LESTRE 3001 12E AVENUE	1200 Fleet street	5623 Green Valley Circle #104
Voice: 37		FAX: 1-310-936-6610
FAX: Quebec NORD	Voice: FAX/CAN	FAX: 1-310-936-6610
SHERBROOKE, QUE	manchest, London UK	Culver City USA

SITE 1 SP PERSONNEL

Gra, P C	Ripoll, Marc C
DSS SPECIALIST	PROJECT PHYSICIAN
IL-10 IN IBD/HIV	KEY PRODUCT MGMT.
USA	USA
Active: 20-Feb-1998	www.tester.com
	Active: 20-Feb-1998

Dunn, Mark C
SITE REQUESTER
WORLDWIDE RSCH QA
USA

Ready 2/26/98 9:52:37

FIS, 64

FORMS

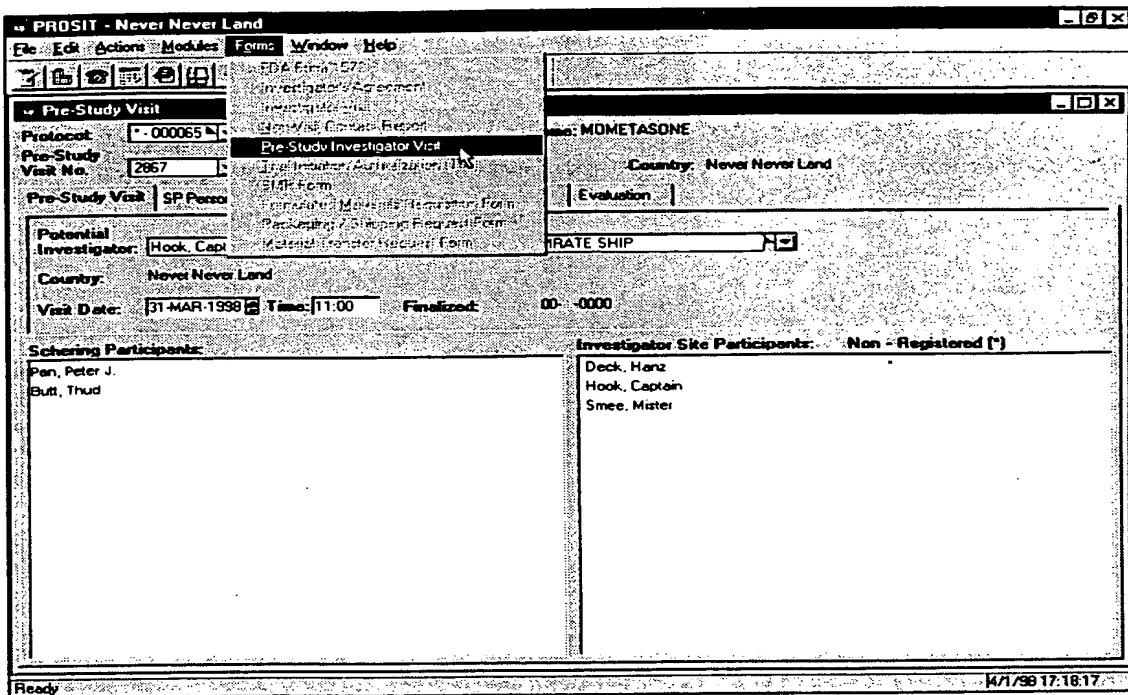


Fig
65

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